

From: Goodrich, April (CDC/NCIRD/ID)
Sent: Wed, 1 May 2024 19:54:50 +0000
To: Barnes, John R. (CDC/NCIRD/ID)
Cc: Kirby, Marie (CDC/NCIRD/ID); Booth, Ruffin (CDC/NCIRD/ID)
Subject: RE: H5 kit remediation scenarios
Attachments: MN-028Rev01 - CDC Influenza rRT-PCR Panel Rebuild Procedure - FILLABLE FORMS.pdf, MN-026 Rev 0 - DestructionDefacing rRT-PCR Panels-FILLABLE.pdf, MN-xxxRev00 - H5 Remediation Plan_RB.docx

Hi John,

I've attached a brief SOP that captures what we discussed with Vic and Jamie. Please let me know if I missed anything.

Lot initiation documentation will be needed for the following:

1. Removal of H5b components from 190124 to be used to send to affected labs, per MN-028
2. Destruction of remaining 190124 kits/components (if applicable) per MN-026
3. Manufacture of H5b by DSR per PS-016 (will a new lot number be assigned?)
4. Destruction of old H5b from 220307 & 220303 per MN-026
5. Rebuild of 220307 and 220303 with new H5b per MN-028

I also had a few questions:

1. Will QC perform any testing on the 190124 H5b before it is sent out? We should capture this testing with a work order.
2. Is CDC packaging the H5b from 190124 to be sent to labs? Or will this be ATCC?

Thanks,

April

From: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
Sent: Wednesday, May 1, 2024 10:59 AM
To: Goodrich, April (CDC/NCIRD/ID) <xbn6@cdc.gov>
Cc: Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>; Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>
Subject: H5 kit remediation scenarios
Importance: High

April,

I need your brain. As you have heard we are in the midst of a recall of the H5b target for eventually lots '303 and '307. ~140 kits are out in the field. We need to work through a plan to remediate so we are trying to propose potential processes to ATCC to help us get timelines to make the final decisions.

Possibilities:

(b)(5)

(b)(5)

Can you flesh out these scenarios? We need to present something cohesive for each of these ideas. We will definitely need Option 4 so we need to work through what we would ask for that time estimate.

Thanks so much!

John

John R Barnes, Ph.D.
He/Him
Deputy Branch Chief for Science (Acting)
Virology Surveillance and Diagnosis Branch
DDID/NCIRD/ Influenza Division
Centers for Disease Control and Prevention
404-639-2434 w
404-353-9024 c
fzq9@cdc.gov

	CDC/DDID/NCIRD/ID	Virology, Surveillance and Diagnosis Branch	No.: MN-028
Approved Effective Date: October 3, 2022	Title: CDC Influenza rRT-PCR Panel Rebuild Procedure		Revision 1 Page 3 of 5

Attachment A – Panel/Kit(s) Rebuild Initiation

Indicate Panel/Kit(s) and/or Component(s) for Rebuild

Panel/Kit(s) Catalog Number and/or Description	Panel/Kit(s) Lot Number	Panel/Kit(s) Expiration Date	Component(s) Involved in Rebuild			Unused Component(s)		
			Description	Catalog Number	Quantity	Description	Catalog Number	Quantity

Attach additional information if applicable for panel/kit(s) and associated components involved in rebuild.

Any required labeling will be provided as an attachment to initiation documentation.

Final Rebuilt Panel/Kit

Lot initiation _____

Total Kits _____

Lot Number _____

Expiration Date* _____

*NOTE: Lot Number and Expiration Date are assigned by CDC Influenza Division

Comments: _____

Manufacturing Manager or Designee Signature/Date:	
CDC VSDB SME or Designee Signature/Date:	
Quality Assurance Signature/Date:	

CDC	CDC/DDID/NCIRD/ID	Virology, Surveillance and Diagnosis Branch	No.: MN-028
Approved Effective Date: October 3, 2022		Title: CDC Influenza rRT-PCR Panel Rebuild Procedure	Revision 1 Page 4 of 5

Attachment B – Panel/Kit(s) Rebuild Configuration

Complete the diagram below as appropriate for the new configuration.

Note: Title of configuration does not indicate final regulatory designation for the rebuilt kit

- In-Vitro Diagnostic (IVD) Configuration
- Fluted partition

#1	#2	#3	#4	#5	#6	#7	#8	#9	#10	#11	#12	#13	#14	#15

Indicate position of each component for rebuild

- Research Use Only Oligonucleotide Configuration
- 35 position cardboard box

Indicate position of each component for rebuild

Manufacturing Manager or Designee Signature/Date:	
CDC VSDB SME or Designee Signature/Date:	
Quality Assurance Signature/Date:	

	CDC/DDID/NCIRD/ID	Virology, Surveillance and Diagnosis Branch	No.: MN-028
Approved Effective Date: October 3, 2022		Title: CDC Influenza rRT-PCR Panel Rebuild Procedure	Revision 1 Page 5 of 5

Attachment C: Panel/Kit(s) Rebuild Documentation

Complete as needed for each panel/kit(s) included in rebuild activity.

Product Number				
Lot Number				
Indicate components/quantity to be used in rebuild:	<input type="checkbox"/> Oligonucleotides <input type="checkbox"/> InfA Qty: _____ <input type="checkbox"/> pdm InfA Qty: _____ <input type="checkbox"/> InfB Qty: _____ <input type="checkbox"/> pdm H1 Qty: _____ <input type="checkbox"/> RP Qty: _____ <input type="checkbox"/> H5a Qty: _____ <input type="checkbox"/> H1 Qty: _____ <input type="checkbox"/> H5b Qty: _____ <input type="checkbox"/> H3 Qty: _____ <input type="checkbox"/> FluSC2 Qty: _____ <input type="checkbox"/> Other (See comments)			
	<input type="checkbox"/> Control Materials <input type="checkbox"/> HSC Qty: _____ <input type="checkbox"/> IBPC Qty: _____ <input type="checkbox"/> SIPC Qty: _____ <input type="checkbox"/> EuH7PC Qty: _____ <input type="checkbox"/> H5VC Qty: _____ <input type="checkbox"/> SC2 PC Qty: _____ <input type="checkbox"/> Other (See comments)			
Line clearance performed and verified:	<input type="checkbox"/> Yes <input type="checkbox"/> No Initials: _____			
Quantity of Unused Components:				

Persons conducting rework: Print Name	Signature and Date

Comments: _____

ATCC and/or applicable vendor to complete:

Panel/Kit(s) Rebuild has been completed, the device history record reviewed and acceptable	<input type="checkbox"/> Yes <input type="checkbox"/> No
Signature and Date	

CDC to complete

Manufacturing Manager Signature/Date:	
CDC VSDB SME or Designee Signature/Date:	
Quality Assurance Signature/Date:	

	CDC/OID/NCIRD/ID	Virus Surveillance and Diagnosis Branch	No.: MN-026
Approved Effective Date: April 11, 2013	Title: Destruction/Defacing of CDC Influenza rRT-PCR Panels	Revision 0	Page 3 of 4

Attachment A – Initiation for Destruction/Defacing *In-Vitro Diagnostic (IVD) Kits and Associated Kit Components*

Indicate Items for Destruction/Defacing

- | | |
|--|--|
| <input type="checkbox"/> Initiation for Destruction/Defacing | <input type="checkbox"/> Complete Kit |
| <input type="checkbox"/> Lot Number _____ | <input type="checkbox"/> Specific Kit Components |
| <input type="checkbox"/> Expiration Date _____ | <input type="checkbox"/> Oligonucleotides |
| | <input type="checkbox"/> Control Materials |
| | <input type="checkbox"/> Package Insert |
| | <input type="checkbox"/> Other: _____ |

*NOTE: Lot Number and Expiration Date are assigned by CDC Influenza Division

Comments: _____

Manufacturing Manager:		Date:	
CDC VSDB SME or Designee:		Date:	
Quality Assurance:		Date:	

	CDC/OID/NCIRD/ID	Virus Surveillance and Diagnosis Branch	No.: MN-026
	Approved Effective Date: April 11, 2013	Title: Destruction/Defacing of CDC Influenza rRT-PCR Panels	Revision 0 Page 4 of 4

Attachment B: Destruction/Defacing Verification

Product Catalog Number	
Lot Number	
Indicate Kit Components to be Destroyed	<input type="checkbox"/> Entire Kit <input type="checkbox"/> Oligonucleotides <input type="checkbox"/> Control Materials <input type="checkbox"/> Package Insert
Quantity to Destroy/Deface	
Line clearance performed and verified?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If applicable, indicate kit components and quantity NOT destroyed/defaced	
Method of destruction (autoclave, general waste disposal, etc.)	
Persons conducting defacing/destruction noted in the device history record?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Comments:

ATCC and/or applicable vendor to complete

Destruction/Defacing has been completed, the device history record reviewed and acceptable	<input type="checkbox"/> Yes <input type="checkbox"/> No
Signature and Date	

CDC to Complete

Manufacturing Manager:		Date:	
CDC VSDB SME or Designee:		Date:	
Quality Assurance:		Date:	

From: Barnes, John R. (CDC/NCIRD/ID)
Sent: Wed, 1 May 2024 21:25:10 +0000
To: Goodrich, April (CDC/NCIRD/ID)
Cc: Kirby, Marie (CDC/NCIRD/ID); Booth, Ruffin (CDC/NCIRD/ID)
Subject: RE: H5 kit remediation scenarios

Great! Thanks April.

From: Goodrich, April (CDC/NCIRD/ID) <xbn6@cdc.gov>
Sent: Wednesday, May 1, 2024 3:55 PM
To: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
Cc: Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>; Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>
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John

John R Barnes, Ph.D.

He/Him

Deputy Branch Chief for Science (Acting)

Virology Surveillance and Diagnosis Branch

DDID/NCIRD/ Influenza Division

Centers for Disease Control and Prevention

404-639-2434 w

404-353-9024 c

fzg9@cdc.gov

From: Uyeki, Timothy M. (CDC/NCIRD/ID)
Sent: Fri, 17 May 2024 13:39:51 +0000
To: Booth, Ruffin (CDC/NCIRD/ID)
Cc: Barnes, John R. (CDC/NCIRD/ID); Kirby, Marie (CDC/NCIRD/ID); Ivey, Melissa (CDC/IOD/OLSS/OD); Goodrich, April (CDC/NCIRD/ID)
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

No worries. It will be helpful to be looped in when these issues occur in the future so I am aware. Vivien told me about this situation.

From: Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>
Sent: Friday, May 17, 2024 9:26 AM
To: Uyeki, Timothy M. (CDC/NCIRD/ID) <tmu0@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>; Ivey, Melissa (CDC/IOD/OLSS/OD) <mtq3@cdc.gov>; Goodrich, April (CDC/NCIRD/ID) <xbn6@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi Tim,
That is what happens when I assume...
Thanks very much,
Ruffin

From: Uyeki, Timothy M. (CDC/NCIRD/ID) <tmu0@cdc.gov>
Sent: Friday, May 17, 2024 9:24 AM
To: Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>; Ivey, Melissa (CDC/IOD/OLSS/OD) <mtq3@cdc.gov>; Goodrich, April (CDC/NCIRD/ID) <xbn6@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi Ruffin – fortunately, I am aware of the issues on this topic, otherwise some background would have been useful. I think it looks fine. I added some very minor suggested edits for consideration.
Thanks,
Tim

From: Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>
Sent: Friday, May 17, 2024 7:06 AM
To: Uyeki, Timothy M. (CDC/NCIRD/ID) <tmu0@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>; Ivey, Melissa (CDC/IOD/OLSS/OD) <mtq3@cdc.gov>; Goodrich, April (CDC/NCIRD/ID) <xbn6@cdc.gov>
Subject: FW: Health Hazard Evaluation - H5b Correction 5-16-2024

Good morning Tim,
We are preparing a Health Hazard Evaluation for submission to FDA with the recall notice. Can you look this over from a medical perspective to make sure we do not say something that is incorrect?
Thank you very much!
Ruffin

From: Ivey, Melissa (CDC/IOD/OLSS/OD) <mtq3@cdc.gov>
Sent: Thursday, May 16, 2024 3:43 PM
To: Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>; Goodrich, April (CDC/NCIRD/ID) <xbn6@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Here are my edits. Take them or leave them! Overall I think it looks good.

==

Melissa (Mel) Ivey, M.S., CQPA

Acting Lead, Regulatory Affairs Activity (RAA)
Quality Manager, Office of Laboratory Science (OLSci)
Office of Laboratory Science and Safety (OLSS)
Centers for Disease Control & Prevention
M-F 7:30a-4:00p
P: 404-639-1673 | C: 919-889-9514 | E: mtq3@cdc.gov

OLSS is an ISO 9001 certified organization

From: Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>
Sent: Thursday, May 16, 2024 3:22 PM
To: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>; Ivey, Melissa (CDC/IOD/OLSS/OD) <mtq3@cdc.gov>; Goodrich, April (CDC/NCIRD/ID) <xbn6@cdc.gov>
Subject: Health Hazard Evaluation - H5b Correction 5-16-2024

Time for another review.

Thanks!

From: Booth, Ruffin (CDC/NCIRD/ID)
Sent: Fri, 17 May 2024 13:42:58 +0000
To: Barnes, John R. (CDC/NCIRD/ID); Kirby, Marie (CDC/NCIRD/ID); Ivey, Melissa (CDC/IOD/OLSS/OD); Goodrich, April (CDC/NCIRD/ID)
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024
Attachments: Health Hazard Evaluation - H5b Correction 5-16-2024_MLI tu.docx

Hi all,

Attached is the HHE with Tim's suggestions added. I will send to James and go from there.

Thanks,

Ruffin

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*Acting Lead, Regulatory Affairs Activity (RAA)
Quality Manager, Office of Laboratory Science (OLSci)
Office of Laboratory Science and Safety (OLSS)
Centers for Disease Control & Prevention
M-F 7:30a-4:00p
P: 404-639-1673 | C: 919-889-9514 | E: mtq3@cdc.gov*

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From: Booth, Ruffin (CDC/NCIRD/ID) <ihi5@cdc.gov>
Sent: Thursday, May 16, 2024 3:22 PM
To: Barnes, John R. (CDC/NCIRD/ID) <fzg9@cdc.gov>; Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>;
Ivey, Melissa (CDC/IOD/OLSS/OD) <mtq3@cdc.gov>; Goodrich, April (CDC/NCIRD/ID) <xbn6@cdc.gov>
Subject: Health Hazard Evaluation - H5b Correction 5-16-2024

Time for another review.

Thanks!

From: Stevens, James (CDC/NCIRD/ID)
Sent: Fri, 17 May 2024 21:52:44 +0000
To: Limbago, Brandi (CDC/NCIRD/OD); Daskalakis, Demetre (CDC/NCIRD/OD);
Booth, Ruffin (CDC/NCIRD/ID); Barnes, John R. (CDC/NCIRD/ID)
Cc: Dugan, Vivien (CDC/NCIRD/ID); Kuehl, Debra B. (CDC/NCIRD/OD)
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Thanks Brandi

James Stevens, Ph.D.
Associate Director for Laboratory Sciences (Acting)
National Center for Immunization and Respiratory Disease
NCIRD, Centers for Disease Control and Prevention
1600 Clifton Rd - Mail stop H23-6
Atlanta, GA 30329-4027
Phone (404)-639-5008; Cell: (404)-384-8795

From: Limbago, Brandi (CDC/NCIRD/OD) <bbi7@cdc.gov>
Sent: Friday, May 17, 2024 5:49 PM
To: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>; Daskalakis, Demetre (CDC/NCIRD/OD) <yza5@cdc.gov>; Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
Cc: Dugan, Vivien (CDC/NCIRD/ID) <lny1@cdc.gov>; Kuehl, Debra B. (CDC/NCIRD/OD) <dpk6@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

I have one small edit to the first response of the hazard narrative. If this is okay with you, I will make the edit and return to Demetre to share up

(b)(5)

From: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Sent: Friday, May 17, 2024 5:47 PM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <yza5@cdc.gov>; Limbago, Brandi (CDC/NCIRD/OD) <bbi7@cdc.gov>; Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
Cc: Dugan, Vivien (CDC/NCIRD/ID) <lny1@cdc.gov>; Kuehl, Debra B. (CDC/NCIRD/OD) <dpk6@cdc.gov>
Subject: Re: Health Hazard Evaluation - H5b Correction 5-16-2024

Thanks Demetre.

If you could please share up to IOD that would be great. Once IOD completes their review, adding appropriate contact details for the CDC Director and clears them, they will need to be returned to Ruffin Booth and John Barnes so they can be submitted.

Thanks again
James

James Stevens, Ph.D.

Associate Director for Laboratory Sciences (Acting)

National Center for Immunization and Respiratory Disease

NCIRD, Centers for Disease Control and Prevention

1600 Clifton Rd - Mail stop H23-6

Atlanta, GA 30329-4027

Phone (404)-639-5008; Cell: (404)-384-8795

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Friday, May 17, 2024 5:36 PM
To: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>; Limbago, Brandi (CDC/NCIRD/OD) <bb17@cdc.gov>
Cc: Booth, Ruffin (CDC/NCIRD/ID) <[ijw5@cdc.gov](mailto:iwj5@cdc.gov)>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Dugan, Vivien (CDC/NCIRD/ID) <lny1@cdc.gov>; Kuehl, Debra B. (CDC/NCIRD/OD) <dpk6@cdc.gov>
Subject: Re: Health Hazard Evaluation - H5b Correction 5-16-2024

These look great. Do you need me to send to Kate?

Get [Outlook for iOS](#)

From: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Sent: Friday, May 17, 2024 4:33:12 PM
To: Limbago, Brandi (CDC/NCIRD/OD) <bb17@cdc.gov>; Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Booth, Ruffin (CDC/NCIRD/ID) <[ijw5@cdc.gov](mailto:iwj5@cdc.gov)>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Dugan, Vivien (CDC/NCIRD/ID) <lny1@cdc.gov>; Kuehl, Debra B. (CDC/NCIRD/OD) <dpk6@cdc.gov>
Subject: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi Demetre and Brandi,

For the H5 kit primer issue, attached are copies of the Health Hazard Evaluation, and the FDA Recall Notice that needs to be sent to FDA.

Please take a look let us know if you have any questions/edits. Once Center approves these, we will then need to send this up to OID.

Dr. Cohen is the listed 'Top Firm' official in the recall notice form and OID will need edit and clear this section and provide appropriate contact information for Dr. Cohen (email/phone).

Many thanks for your help

James

James Stevens, Ph.D.

Associate Director for Laboratory Sciences (Acting)

National Center for Immunization and Respiratory Disease

NCIRD, Centers for Disease Control and Prevention

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Atlanta, GA 30329-4027

Phone (404)-639-5008; Cell: (404)-384-8795

From: Daskalakis, Demetre (CDC/NCIRD/OD)
Sent: Wed, 22 May 2024 17:56:35 +0000
To: Stevens, James (CDC/NCIRD/ID); Limbago, Brandi (CDC/NCIRD/OD); Booth, Ruffin (CDC/NCIRD/ID); Barnes, John R. (CDC/NCIRD/ID)
Cc: Dugan, Vivien (CDC/NCIRD/ID); Kuehl, Debra B. (CDC/NCIRD/OD)
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Of course! Thank you!

From: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Sent: Wednesday, May 22, 2024 1:36 PM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>; Limbago, Brandi (CDC/NCIRD/OD) <bbi7@cdc.gov>; Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
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Subject: Re: Health Hazard Evaluation - H5b Correction 5-16-2024

No problem.

Thanks for sending it up

James Stevens, Ph.D.

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National Center for Immunization and Respiratory Disease

NCIRD, Centers for Disease Control and Prevention

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Phone (404)-639-5008; Cell: (404)-384-8795

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Sent: Wednesday, May 22, 2024 1:32 PM
To: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>; Limbago, Brandi (CDC/NCIRD/OD) <bbi7@cdc.gov>; Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
Cc: Dugan, Vivien (CDC/NCIRD/ID) <lny1@cdc.gov>; Kuehl, Debra B. (CDC/NCIRD/OD) <dpk6@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

I managed not to send on Friday. Just sent up. I am sorry, I thought Brandi was going to send.

From: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Sent: Wednesday, May 22, 2024 1:21 PM
To: Limbago, Brandi (CDC/NCIRD/OD) <bb17@cdc.gov>; Daskalakis, Demetre (CDC/NCIRD/OD) <yqz5@cdc.gov>; Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
Cc: Dugan, Vivien (CDC/NCIRD/ID) <lny1@cdc.gov>; Kuehl, Debra B. (CDC/NCIRD/OD) <dpk6@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi Demetre,

Apologies I would ask Brandi, (b)(6) Have you heard back from IOD with their document review and adding the CDC Director's details to the FDA primer correction documents we sent up on Friday? Would be good to get these finalized and submitted to FDA if we can.

Many thanks

James

James Stevens, Ph.D.
Associate Director for Laboratory Sciences (Acting)
National Center for Immunization and Respiratory Disease
NCIRD, Centers for Disease Control and Prevention
1600 Clifton Rd - Mail stop H23-6
Atlanta, GA 30329-4027
Phone (404)-639-5008; Cell: (404)-384-8795

From: Limbago, Brandi (CDC/NCIRD/OD) <bb17@cdc.gov>
Sent: Friday, May 17, 2024 5:49 PM
To: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>; Daskalakis, Demetre (CDC/NCIRD/OD) <yqz5@cdc.gov>; Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
Cc: Dugan, Vivien (CDC/NCIRD/ID) <lny1@cdc.gov>; Kuehl, Debra B. (CDC/NCIRD/OD) <dpk6@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

I have one small edit to the first response of the hazard narrative. If this is okay with you, I will make the edit and return to Demetre to share up

(b)(5)

From: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Sent: Friday, May 17, 2024 5:47 PM

To: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>; Limbago, Brandi (CDC/NCIRD/OD) <bbi7@cdc.gov>; Booth, Ruffin (CDC/NCIRD/ID) <ihi5@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
Cc: Dugan, Vivien (CDC/NCIRD/ID) <lny1@cdc.gov>; Kuehl, Debra B. (CDC/NCIRD/OD) <dpk6@cdc.gov>
Subject: Re: Health Hazard Evaluation - H5b Correction 5-16-2024

Thanks Demetre.

If you could please share up to IOD that would be great. Once IOD completes their review, adding appropriate contact details for the CDC Director and clears them, they will need to be returned to Ruffin Booth and John Barnes so they can be submitted.

Thanks again

James

James Stevens, Ph.D.

Associate Director for Laboratory Sciences (Acting)

National Center for Immunization and Respiratory Disease

NCIRD, Centers for Disease Control and Prevention

1600 Clifton Rd - Mail stop H23-6

Atlanta, GA 30329-4027

Phone (404)-639-5008; Cell: (404)-384-8795

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Friday, May 17, 2024 5:36 PM
To: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>; Limbago, Brandi (CDC/NCIRD/OD) <bbi7@cdc.gov>
Cc: Booth, Ruffin (CDC/NCIRD/ID) <ihi5@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Dugan, Vivien (CDC/NCIRD/ID) <lny1@cdc.gov>; Kuehl, Debra B. (CDC/NCIRD/OD) <dpk6@cdc.gov>
Subject: Re: Health Hazard Evaluation - H5b Correction 5-16-2024

These look great. Do you need me to send to Kate?

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From: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Sent: Friday, May 17, 2024 4:33:12 PM
To: Limbago, Brandi (CDC/NCIRD/OD) <bbi7@cdc.gov>; Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Booth, Ruffin (CDC/NCIRD/ID) <ihi5@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>;

Dugan, Vivien (CDC/NCIRD/ID) <lny1@cdc.gov>; Kuehl, Debra B. (CDC/NCIRD/OD) <dpk6@cdc.gov>
Subject: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi Demetre and Brandi,

For the H5 kit primer issue, attached are copies of the Health Hazard Evaluation, and the FDA Recall Notice that needs to be sent to FDA.

Please take a look let us know if you have any questions/edits. Once Center approves these, we will then need to send this up to OID.

Dr. Cohen is the listed 'Top Firm' official in the recall notice form and OID will need edit and clear this section and provide appropriate contact information for Dr. Cohen (email/phone).

Many thanks for your help

James

James Stevens, Ph.D.

Associate Director for Laboratory Sciences (Acting)

National Center for Immunization and Respiratory Disease

NCIRD, Centers for Disease Control and Prevention

1600 Clifton Rd - Mail stop H23-6

Atlanta, GA 30329-4027

Phone (404)-639-5008; Cell: (404)-384-8795

From: Daskalakis, Demetre (CDC/NCIRD/OD)
Sent: Tue, 28 May 2024 13:13:08 +0000
To: Stevens, James (CDC/NCIRD/ID)
Cc: Barnes, John R. (CDC/NCIRD/ID); Booth, Ruffin (CDC/NCIRD/ID)
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

No, nothing yet. Will ping

From: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Sent: Tuesday, May 28, 2024 8:31 AM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Booth, Ruffin (CDC/NCIRD/ID) <[ijw5@cdc.gov](mailto:iwj5@cdc.gov)>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi Demetre,
Did we hear back from IOD on the FDA correction paperwork?
We should try to submit this soon 😊
Many thanks
James

James Stevens, Ph.D.
Associate Director for Laboratory Sciences
Influenza Division, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Rd - Mail stop H23-6
Atlanta, GA 30329-4027
Phone (404)-639-5008; Cell: (404)-384-8795

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Thursday, May 23, 2024 12:09 PM
To: Booth, Ruffin (CDC/NCIRD/ID) <ijw5@cdc.gov>; Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Thanks! Communicating that to iOD

From: Booth, Ruffin (CDC/NCIRD/ID) <ijw5@cdc.gov>
Sent: Thursday, May 23, 2024 12:07 PM
To: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>; Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi James, Demetre,

Not all of the document will be public. I have attached an example of the information FDA pulls for the public facing website post. The CDC Director's information should not be public, per a conversation with the FDA Recall Coordinator Team Lead. What will be public is the Recall Contact at Recalling Firm. If desired, the current contact (me) can be changed.

Hope that helps,

Ruffin

Ruffin Booth, ASQ CMQ/OE, CQA, CSSBB; RAPS RAC

Quality Manager

Centers for Disease Control and Prevention, CDC

Influenza Division

Bldg 24, 7136, MS H24-7

Office: 404-639-1947

Cell: 404-263-2667

RBooth1@cdc.gov

From: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>

Sent: Thursday, May 23, 2024 11:22 AM

To: Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>

Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>

Subject: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi Ruffin/John,

Demetre got a question back from IOD asking if the document will be a public document?

I'm assuming we do not want to provide the CDC Directors direct contact details if there is a chance it is. Can you please let us know. I'm falling on the side that if there is even a chance we should provide non-private contact information.

Thoughts? Is the document made public?

Thanks

James

James Stevens, Ph.D.

Associate Director for Laboratory Sciences (Acting)

National Center for Immunization and Respiratory Disease

NCIRD, Centers for Disease Control and Prevention

1600 Clifton Rd - Mail stop H23-6

Atlanta, GA 30329-4027

Phone (404)-639-5008; Cell: (404)-384-8795

From: Daskalakis, Demetre (CDC/NCIRD/OD)
Sent: Thu, 23 May 2024 16:09:07 +0000
To: Wolff, Kate L. (CDC/IOD/OCS)
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR); Shah, Nirav (CDC/IOD)
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024
Attachments: EXAMPLE - Class 2 Device Recall WishFIX Growth Control Plating System.pdf

Not all of the document will be public. I have attached an example of the information FDA pulls for the public facing website post. The CDC Director's information should not be public, per a conversation with the FDA Recall Coordinator Team Lead. What will be public is the Recall Contact at Recalling Firm.

From: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Sent: Thursday, May 23, 2024 11:10 AM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Got it – and is this a public document?

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Thursday, May 23, 2024 9:40 AM
To: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Yes. Also happy to take any additional feedback. I know it's a technical communication, but wanted to make sure I got any feedback.

From: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Sent: Thursday, May 23, 2024 9:19 AM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi – want to make sure I understand the ask here – you need the appropriate phone and email address for the director? Is there something else that we would need to do for this?

The phone should be CDC main line: 800-232-4636
Email address is: (b)(6) @cdc.gov

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Wednesday, May 22, 2024 1:32 PM
To: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: Health Hazard Evaluation - H5b Correction 5-16-2024

Kate-

See attached and below- We have to send this over to the FDA after you all have reviewed and added the desired information for MKC.

For the H5 kit primer issue, attached are copies of the Health Hazard Evaluation, and the FDA Recall Notice that needs to be sent to FDA.

Dr. Cohen is the listed 'Top Firm' official in the recall notice form and OID will need edit and clear this section and provide appropriate contact information for Dr. Cohen.

Thanks

Demetre



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Class 2 Device Recall WishFIX Growth Control Plating System



[§10\(k\)⁷](#) | [DeNovo⁸](#) | [Registration & Listing⁹](#) | [Adverse Events¹⁰](#) | [Recalls¹¹](#) | [PMA¹²](#) | [HDE¹³](#) | [Classification¹⁴](#) | [Standards¹⁵](#)
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Class 2 Device Recall WishFIX Growth Control Plating System

See Related Information

22

Date Initiated by Firm	April 05, 2024
Date Posted	May 10, 2024
Recall Status ¹	Open ³ , Classified
Recall Number	Z-1808-2024
Recall Event ID	94405²³
510(K)Number	K182704²⁴
Product Classification	Plate, bone, growth control, pediatric, epiphysiodesis²⁵ - Product Code OBT²⁶
Product	WishFIX Growth Control Plating System, Model Number: TEFCS28-080US. Orthopedic device.
Code Information	Model Number: TEFCS28-08-US; UDI/DI: B562TEFCS2808US0; Lot Number: 28042
Recalling Firm/ Manufacturer	Wishbone Medical, Inc. 100 Capital Dr Warsaw IN 46582-6704
For Additional Information Contact	Brandon Alger 574-306-4006
Manufacturer Reason for Recall	The products in this lot are incorrectly packed with a Stainless-Steel implant instead of a Titanium implant as the packaging and part number indicated.
FDA Determined Cause ²	Nonconforming Material/Component

Action	On April 5, 2024 an email with an attached MEDICAL DEVICE RECALL NOTICE was sent to all Sales Representatives, Distributors, Institutions, and Physicians who have received a product from the affected lot. Immediate Actions to Take as the Customer/User: 1. Complete and return the attached response form via email (see below) or post mail to the address below. Please complete this form even if you do not have any of this product on hand. 2. Please examine your inventory for affected devices. 3. Please return any affected product either to your distributor or to WishBone Medical at: WishBone Medical, Inc., 100 Capital Drive, Warsaw, IN 46582. 4. Once the product has been received by the WishBone Medical office, customer service will confirm whether you would like replacement product sent. 5. If you have already disposed of product or if it has already been implanted, please note this on the Acknowledgement and Response Form for credit to your account. Please maintain this notice on file for your company's awareness. This recall is being conducted with the knowledge of FDA and is subject to FDA effectiveness checks.
Quantity in Commerce	60 units
Distribution	US distribution to Florida, New Jersey and Connecticut.
Total Product Life Cycle	TPLC Device Report ²⁷

¹ A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about [medical device recalls](#)²⁸.

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

³ The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database [510\(K\)s with Product Code = OBT and Original Applicant = WishBone Medical](#)²⁹

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22. <http://www.fda.gov/safety/recalls/enforcementreports/default.htm>
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=94405
24. </scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K182704>
25. </scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=OBT>
26. </scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=OBT>
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28. <http://www.fda.gov/MedicalDevices/Safety>ListofRecalls/ucm329946.htm>
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=OBT&knumber=&applicant=WishBone%20Medical

Page Last Updated: 05/22/2024

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22. <http://www.fda.gov/safety/recalls/enforcementreports/default.htm>
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28. <http://www.fda.gov/MedicalDevices/Safety>ListofRecalls/ucm329946.htm>
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=OBT&knumber=&applicant=WishBone%20Medical

From: Ivey, Melissa (CDC/IOD/OLSS/OD)
Sent: Fri, 17 May 2024 14:45:25 +0000
To: Barnes, John R. (CDC/NCIRD/ID); Booth, Ruffin (CDC/NCIRD/ID); Kirby, Marie (CDC/NCIRD/ID); Goodrich, April (CDC/NCIRD/ID)
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Looks good to me as well.

==

Melissa (Mel) Ivey, M.S., CQPA

Acting Lead, Regulatory Affairs Activity (RAA)
Quality Manager, Office of Laboratory Science (OLSci)
Office of Laboratory Science and Safety (OLSS)
Centers for Disease Control & Prevention
M-F 7:30a-4:00p
P: 404-639-1673 | C: 919-889-9514 | E: mtq3@cdc.gov

OLSS is an ISO 9001 certified organization

From: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
Sent: Friday, May 17, 2024 9:44 AM
To: Booth, Ruffin (CDC/NCIRD/ID) <[ijh5@cdc.gov](mailto:iwj5@cdc.gov)>; Kirby, Marie (CDC/NCIRD/ID) <pbj0@cdc.gov>; Ivey, Melissa (CDC/IOD/OLSS/OD) <mtq3@cdc.gov>; Goodrich, April (CDC/NCIRD/ID) <xbn6@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Looks good to me. Thanks!

From: Booth, Ruffin (CDC/NCIRD/ID) <[ijh5@cdc.gov](mailto:iwj5@cdc.gov)>
Sent: Friday, May 17, 2024 9:43 AM
To: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Kirby, Marie (CDC/NCIRD/ID) <pbj0@cdc.gov>; Ivey, Melissa (CDC/IOD/OLSS/OD) <mtq3@cdc.gov>; Goodrich, April (CDC/NCIRD/ID) <xbn6@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi all,

Attached is the HHE with Tim's suggestions added. I will send to James and go from there.

Thanks,

Ruffin

From: Uyeki, Timothy M. (CDC/NCIRD/ID) <tmu0@cdc.gov>
Sent: Friday, May 17, 2024 9:24 AM
To: Booth, Ruffin (CDC/NCIRD/ID) <[ijh5@cdc.gov](mailto:iwj5@cdc.gov)>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Kirby, Marie (CDC/NCIRD/ID) <pbj0@cdc.gov>; Ivey, Melissa (CDC/IOD/OLSS/OD) <mtq3@cdc.gov>; Goodrich, April (CDC/NCIRD/ID) <xbn6@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi Ruffin – fortunately, I am aware of the issues on this topic, otherwise some background would have been useful. I think it looks fine. I added some very minor suggested edits for consideration.

Thanks,
Tim

From: Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>
Sent: Friday, May 17, 2024 7:06 AM
To: Uyeki, Timothy M. (CDC/NCIRD/ID) <tmu0@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>;
Ivey, Melissa (CDC/IOD/OLSS/OD) <mtq3@cdc.gov>; Goodrich, April (CDC/NCIRD/ID) <xbn6@cdc.gov>
Subject: FW: Health Hazard Evaluation - H5b Correction 5-16-2024

Good morning Tim,
We are preparing a Health Hazard Evaluation for submission to FDA with the recall notice. Can you look this over from a medical perspective to make sure we do not say something that is incorrect?
Thank you very much!
Ruffin

From: Ivey, Melissa (CDC/IOD/OLSS/OD) <mtq3@cdc.gov>
Sent: Thursday, May 16, 2024 3:43 PM
To: Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>;
Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>; Goodrich, April (CDC/NCIRD/ID) <xbn6@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Here are my edits. Take them or leave them! Overall I think it looks good.

==

Melissa (Mel) Ivey, M.S., CQPA

*Acting Lead, Regulatory Affairs Activity (RAA)
Quality Manager, Office of Laboratory Science (OLSci)
Office of Laboratory Science and Safety (OLSS)
Centers for Disease Control & Prevention
M-F 7:30a-4:00p
P: 404-639-1673 | C: 919-889-9514 | E: mtq3@cdc.gov*

OLSS is an ISO 9001 certified organization

From: Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>
Sent: Thursday, May 16, 2024 3:22 PM
To: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>;
Ivey, Melissa (CDC/IOD/OLSS/OD) <mtq3@cdc.gov>; Goodrich, April (CDC/NCIRD/ID) <xbn6@cdc.gov>
Subject: Health Hazard Evaluation - H5b Correction 5-16-2024

Time for another review.
Thanks!

From: Booth, Ruffin (CDC/NCIRD/ID)
Sent: Tue, 28 May 2024 23:09:27 +0000
To: Stevens, James (CDC/NCIRD/ID); Barnes, John R. (CDC/NCIRD/ID)
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

I will ask Mel. Can't hurt.

From: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Sent: Tuesday, May 28, 2024 7:08 PM
To: Barnes, John R. (CDC/NCIRD/ID) <fqz9@cdc.gov>; Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>
Subject: Re: Health Hazard Evaluation - H5b Correction 5-16-2024

can you push for CDC reg to ask as well?

James Stevens, Ph.D.

Associate Director for Laboratory Sciences

Influenza Division, NCIRD

Centers for Disease Control and Prevention

1600 Clifton Rd - Mail stop H23-6

Atlanta, GA 30329-4027

Phone (404)-639-5008; Cell: (404)-384-8795

From: Barnes, John R. (CDC/NCIRD/ID) <fqz9@cdc.gov>
Sent: Tuesday, May 28, 2024 6:27 PM
To: Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>; Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
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Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

I am worried about what we will get back and when.....

From: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Sent: Tuesday, May 28, 2024 6:24 PM
To: Booth, Ruffin (CDC/NCIRD/ID) <[ijw5@cdc.gov](mailto:iwj5@cdc.gov)>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
Subject: Re: Health Hazard Evaluation - H5b Correction 5-16-2024

(b)(5)

James Stevens, Ph.D.
Associate Director for Laboratory Sciences
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Sent: Tuesday, May 28, 2024 5:57 PM
To: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Booth, Ruffin (CDC/NCIRD/ID) <ijw5@cdc.gov>
Subject: Re: Health Hazard Evaluation - H5b Correction 5-16-2024

Thanks Demetre

James Stevens, Ph.D.
Associate Director for Laboratory Sciences
Influenza Division, NCIRD

Centers for Disease Control and Prevention

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Atlanta, GA 30329-4027

Phone (404)-639-5008; Cell: (404)-384-8795

From: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
Sent: Tuesday, May 28, 2024 5:56 PM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Booth, Ruffin (CDC/NCIRD/ID) <ihi5@cdc.gov>; Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

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To: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
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FDA is asking the document be submitted back to them this week.

John

From: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Sent: Tuesday, May 28, 2024 8:31 AM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Booth, Ruffin (CDC/NCIRD/ID) <ihi5@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi Demetre,

Did we hear back from IOD on the FDA correction paperwork?

We should try to submit this soon 😊

Many thanks

James

James Stevens, Ph.D.
Associate Director for Laboratory Sciences
Influenza Division, NCIRD
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Phone (404)-639-5008; Cell: (404)-384-8795

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Thursday, May 23, 2024 12:09 PM
To: Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>; Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzg9@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Thanks! Communicating that to iOD

From: Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>
Sent: Thursday, May 23, 2024 12:07 PM
To: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>; Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzg9@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi James, Demetre,
Not all of the document will be public. I have attached an example of the information FDA pulls for the public facing website post. The CDC Director's information should not be public, per a conversation with the FDA Recall Coordinator Team Lead. What will be public is the Recall Contact at Recalling Firm. If desired, the current contact (me) can be changed.
Hope that helps,
Ruffin

Ruffin Booth, ASQ CMQ/OE, CQA, CSSBB; RAPS RAC

Quality Manager
Centers for Disease Control and Prevention, CDC
Influenza Division
Bldg 24, 7136, MS H24-7
Office: 404-639-1947
Cell: 404-263-2667
RBooth1@cdc.gov

From: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Sent: Thursday, May 23, 2024 11:22 AM
To: Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID) <fzg9@cdc.gov>

Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <yqz5@cdc.gov>
Subject: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi Ruffin/John,
Demetre got a question back from IOD asking if the document will be a public document?
I'm assuming we do not want to provide the CDC Directors direct contact details if there is a chance it is.
Can you please let us know. I'm falling on the side that if there is even a chance we should provide non-private contact information.
Thoughts? Is the document made public?
Thanks
James

James Stevens, Ph.D.
Associate Director for Laboratory Sciences (Acting)
National Center for Immunization and Respiratory Disease
NCIRD, Centers for Disease Control and Prevention
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Atlanta, GA 30329-4027
Phone (404)-639-5008; Cell: (404)-384-8795

From: Booth, Ruffin (CDC/NCIRD/ID)
Sent: Wed, 29 May 2024 12:09:03 +0000
To: Stevens, James (CDC/NCIRD/ID); Barnes, John R. (CDC/NCIRD/ID)
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Thanks!
Ruffin

From: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Sent: Wednesday, May 29, 2024 8:00 AM
To: Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Sorry, thought you were on the Demetre email last night.
Just forwarded

James Stevens, Ph.D.
Associate Director for Laboratory Sciences
Influenza Division, NCIRD
Centers for Disease Control and Prevention
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Atlanta, GA 30329-4027
Phone (404)-639-5008; Cell: (404)-384-8795

From: Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>
Sent: Wednesday, May 29, 2024 7:47 AM
To: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Mel does not know who to contact and is in the dark as well. They need a more transparent process.

From: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Sent: Tuesday, May 28, 2024 7:08 PM
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(b)(5)

James Stevens, Ph.D.

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Ruffin Booth, ASQ CMQ/OE, CQA, CSSBB; RAPS RAC

Quality Manager

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Influenza Division

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Cell: 404-263-2667

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Phone (404)-639-5008; Cell: (404)-384-8795

From: Daskalakis, Demetre (CDC/NCIRD/OD)
Sent: Wed, 29 May 2024 12:27:55 +0000
To: Barnes, John R. (CDC/NCIRD/ID); Stevens, James (CDC/NCIRD/ID)
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Thanks for your patience

From: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
Sent: Tuesday, May 28, 2024 8:11 PM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>; Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Subject: Re: Health Hazard Evaluation - H5b Correction 5-16-2024

Thanks so much, Demetre!

Sent via the Samsung Galaxy S20 FE 5G, an AT&T 5G smartphone
Get [Outlook for Android](#)

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Tuesday, May 28, 2024 7:49:34 PM
To: Barnes, John R. (CDC/NCIRD/ID) <[fzq9@cdc.gov](#)>; Stevens, James (CDC/NCIRD/ID) <[fwb4@cdc.gov](#)>
Subject: Fwd: Health Hazard Evaluation - H5b Correction 5-16-2024

We are a go. Please see contact info preferred

Get [Outlook for iOS](#)

From: Wolff, Kate L. (CDC/IOD/OCS) <[uqq9@cdc.gov](#)>
Sent: Tuesday, May 28, 2024 6:49 PM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <[yzq5@cdc.gov](#)>
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <[yyw2@cdc.gov](#)>; Shah, Nirav (CDC/IOD) <[yyy8@cdc.gov](#)>
Subject: Re: Health Hazard Evaluation - H5b Correction 5-16-2024

The phone should be CDC main line: [800-232-4636](#)

Email address is: [\(b\)\(6\) @cdc.gov](#)

From: Daskalakis, Demetre (CDC/NCIRD/OD) <[yzq5@cdc.gov](#)>
Sent: Tuesday, May 28, 2024 5:59:44 PM
To: Wolff, Kate L. (CDC/IOD/OCS) <[uqq9@cdc.gov](#)>
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <[yyw2@cdc.gov](#)>; Shah, Nirav (CDC/IOD) <[yyy8@cdc.gov](#)>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Just need to know the right contact information we should include for MKC. Thx

From: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Sent: Tuesday, May 28, 2024 5:59 PM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: Re: Health Hazard Evaluation - H5b Correction 5-16-2024

Sorry - I think it is fine, let me know if you need something else from me.

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Tuesday, May 28, 2024 5:54:19 PM
To: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Just circling back on this. FDA is requesting that we submit this this week.

Demetre

From: Daskalakis, Demetre (CDC/NCIRD/OD)
Sent: Thursday, May 23, 2024 9:40 AM
To: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Yes. Also happy to take any additional feedback. I know it's a technical communication, but wanted to make sure I got any feedback.

From: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Sent: Thursday, May 23, 2024 9:19 AM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi – want to make sure I understand the ask here – you need the appropriate phone and email address for the director? Is there something else that we would need to do for this?

The phone should be CDC main line: 800-232-4636

Email address is: [\(b\)\(6\)@cdc.gov](mailto:(b)(6)@cdc.gov)

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Wednesday, May 22, 2024 1:32 PM
To: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: Health Hazard Evaluation - H5b Correction 5-16-2024

Kate-

See attached and below- We have to send this over to the FDA after you all have reviewed and added the desired information for MKC.

For the H5 kit primer issue, attached are copies of the Health Hazard Evaluation, and the FDA Recall Notice that needs to be sent to FDA.

Dr. Cohen is the listed 'Top Firm' official in the recall notice form and OID will need edit and clear this section and provide appropriate contact information for Dr. Cohen.

Thanks

Demetre

From: Uyeki, Timothy M. (CDC/NCIRD/ID)
Sent: Fri, 17 May 2024 13:24:18 +0000
To: Booth, Ruffin (CDC/NCIRD/ID)
Cc: Barnes, John R. (CDC/NCIRD/ID); Kirby, Marie (CDC/NCIRD/ID); Ivey, Melissa (CDC/IOD/OLSS/OD); Goodrich, April (CDC/NCIRD/ID)
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024
Attachments: Health Hazard Evaluation - H5b Correction 5-16-2024_MLI tu.docx

Hi Ruffin – fortunately, I am aware of the issues on this topic, otherwise some background would have been useful. I think it looks fine. I added some very minor suggested edits for consideration.

Thanks,
Tim

From: Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>
Sent: Friday, May 17, 2024 7:06 AM
To: Uyeki, Timothy M. (CDC/NCIRD/ID) <ctmu0@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>; Ivey, Melissa (CDC/IOD/OLSS/OD) <mtq3@cdc.gov>; Goodrich, April (CDC/NCIRD/ID) <xbn6@cdc.gov>
Subject: FW: Health Hazard Evaluation - H5b Correction 5-16-2024

Good morning Tim,
We are preparing a Health Hazard Evaluation for submission to FDA with the recall notice. Can you look this over from a medical perspective to make sure we do not say something that is incorrect?
Thank you very much!
Ruffin

From: Ivey, Melissa (CDC/IOD/OLSS/OD) <mtq3@cdc.gov>
Sent: Thursday, May 16, 2024 3:43 PM
To: Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>; Goodrich, April (CDC/NCIRD/ID) <xbn6@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Here are my edits. Take them or leave them! Overall I think it looks good.

==

Melissa (Mel) Ivey, M.S., CQPA

Acting Lead, Regulatory Affairs Activity (RAA)
Quality Manager, Office of Laboratory Science (OLSci)
Office of Laboratory Science and Safety (OLSS)
Centers for Disease Control & Prevention
M-F 7:30a-4:00p
P: 404-639-1673 | C: 919-889-9514 | E: mtq3@cdc.gov

OLSS is an ISO 9001 certified organization

From: Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>
Sent: Thursday, May 16, 2024 3:22 PM
To: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Kirby, Marie (CDC/NCIRD/ID) <pbj0@cdc.gov>; Ivey, Melissa (CDC/IOD/OLSS/OD) <mtq3@cdc.gov>; Goodrich, April (CDC/NCIRD/ID) <xbn6@cdc.gov>
Subject: Health Hazard Evaluation - H5b Correction 5-16-2024

Time for another review.

Thanks!

From: Stevens, James (CDC/NCIRD/ID)
Sent: Wed, 29 May 2024 01:33:12 +0000
To: Daskalakis, Demetre (CDC/NCIRD/OD); Barnes, John R. (CDC/NCIRD/ID)
Subject: Re: Health Hazard Evaluation - H5b Correction 5-16-2024

Thanks Demetre

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From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Tuesday, May 28, 2024 7:49:34 PM
To: Barnes, John R. (CDC/NCIRD/ID) <fzb9@cdc.gov>; Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Subject: Fwd: Health Hazard Evaluation - H5b Correction 5-16-2024

We are a go. Please see contact info preferred

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From: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Sent: Tuesday, May 28, 2024 6:49 PM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: Re: Health Hazard Evaluation - H5b Correction 5-16-2024

The phone should be CDC main line: [800-232-4636](#)

Email address is: (b)(6) @cdc.gov

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Tuesday, May 28, 2024 5:59:44 PM
To: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Just need to know the right contact information we should include for MKC. Thx

From: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Sent: Tuesday, May 28, 2024 5:59 PM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: Re: Health Hazard Evaluation - H5b Correction 5-16-2024

Sorry - I think it is fine, let me know if you need something else from me.

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Tuesday, May 28, 2024 5:54:19 PM
To: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Just circling back on this. FDA is requesting that we submit this this week.

Demetre

From: Daskalakis, Demetre (CDC/NCIRD/OD)
Sent: Thursday, May 23, 2024 9:40 AM
To: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Yes. Also happy to take any additional feedback. I know it's a technical communication, but wanted to make sure I got any feedback.

From: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Sent: Thursday, May 23, 2024 9:19 AM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi – want to make sure I understand the ask here – you need the appropriate phone and email address for the director? Is there something else that we would need to do for this?

The phone should be CDC main line: 800-232-4636
Email address is: [\(b\)\(6\)@cdc.gov](mailto:(b)(6)@cdc.gov)

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Wednesday, May 22, 2024 1:32 PM
To: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: Health Hazard Evaluation - H5b Correction 5-16-2024

Kate-

See attached and below- We have to send this over to the FDA after you all have reviewed and added the desired information for MKC.

For the H5 kit primer issue, attached are copies of the Health Hazard Evaluation, and the FDA Recall Notice that needs to be sent to FDA.

Dr. Cohen is the listed 'Top Firm' official in the recall notice form and OID will need edit and clear this section and provide appropriate contact information for Dr. Cohen.

Thanks

Demetre

From: Barnes, John R. (CDC/NCIRD/ID)
Sent: Sat, 18 May 2024 13:42:26 +0000
To: Booth, Ruffin (CDC/NCIRD/ID)
Subject: Re: Health Hazard Evaluation - H5b Correction 5-16-2024

Yes. Technically
Sent via the Samsung Galaxy S20 FE 5G, an AT&T 5G smartphone
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From: Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>
Sent: Saturday, May 18, 2024 8:28:43 AM
To: Barnes, John R. (CDC/NCIRD/ID) <fqz9@cdc.gov>
Subject: FW: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi John,
Is Brandi's statement correct?
Thanks,
Ruffin

From: Limbago, Brandi (CDC/NCIRD/OD) <bbi7@cdc.gov>
Sent: Friday, May 17, 2024 5:49 PM
To: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>; Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>; Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID) <fqz9@cdc.gov>
Cc: Dugan, Vivien (CDC/NCIRD/ID) <lvy1@cdc.gov>; Kuehl, Debra B. (CDC/NCIRD/OD) <dpk6@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

I have one small edit to the first response of the hazard narrative. If this is okay with you, I will make the edit and return to Demetre to share up

(b)(5)

From: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Sent: Friday, May 17, 2024 5:47 PM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>; Limbago, Brandi (CDC/NCIRD/OD) <bbi7@cdc.gov>; Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID) <fqz9@cdc.gov>
Cc: Dugan, Vivien (CDC/NCIRD/ID) <lvy1@cdc.gov>; Kuehl, Debra B. (CDC/NCIRD/OD) <dpk6@cdc.gov>
Subject: Re: Health Hazard Evaluation - H5b Correction 5-16-2024

Thanks Demetre.

If you could please share up to IOD that would be great. Once IOD completes their review, adding appropriate contact details for the CDC Director and clears them, they will need to be returned to Ruffin Booth and John Barnes so they can be submitted.
Thanks again
James

James Stevens, Ph.D.

Associate Director for Laboratory Sciences (Acting)

National Center for Immunization and Respiratory Disease

NCIRD, Centers for Disease Control and Prevention

1600 Clifton Rd - Mail stop H23-6

Atlanta, GA 30329-4027

Phone (404)-639-5008; Cell: (404)-384-8795

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Friday, May 17, 2024 5:36 PM
To: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>; Limbago, Brandi (CDC/NCIRD/OD) <bbi7@cdc.gov>
Cc: Booth, Ruffin (CDC/NCIRD/ID) <[ijw5@cdc.gov](mailto:iwj5@cdc.gov)>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>;
Dugan, Vivien (CDC/NCIRD/ID) <lny1@cdc.gov>; Kuehl, Debra B. (CDC/NCIRD/OD) <dpk6@cdc.gov>
Subject: Re: Health Hazard Evaluation - H5b Correction 5-16-2024

These look great. Do you need me to send to Kate?

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From: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Sent: Friday, May 17, 2024 4:33:12 PM
To: Limbago, Brandi (CDC/NCIRD/OD) <bbi7@cdc.gov>; Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Booth, Ruffin (CDC/NCIRD/ID) <[ijw5@cdc.gov](mailto:iwj5@cdc.gov)>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>;
Dugan, Vivien (CDC/NCIRD/ID) <lny1@cdc.gov>; Kuehl, Debra B. (CDC/NCIRD/OD) <dpk6@cdc.gov>
Subject: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi Demetre and Brandi,

For the H5 kit primer issue, attached are copies of the Health Hazard Evaluation, and the FDA Recall Notice that needs to be sent to FDA.

Please take a look let us know if you have any questions/edits. Once Center approves these, we will then need to send this up to OID.

Dr. Cohen is the listed 'Top Firm' official in the recall notice form and OID will need edit and clear this section and provide appropriate contact information for Dr. Cohen (email/phone).

Many thanks for your help

James

James Stevens, Ph.D.

Associate Director for Laboratory Sciences (Acting)

National Center for Immunization and Respiratory Disease

NCIRD, Centers for Disease Control and Prevention

1600 Clifton Rd - Mail stop H23-6

Atlanta, GA 30329-4027

Phone (404)-639-5008; Cell: (404)-384-8795

From: Booth, Ruffin (CDC/NCIRD/ID)
Sent: Tue, 28 May 2024 22:18:15 +0000
To: Stevens, James (CDC/NCIRD/ID); Barnes, John R. (CDC/NCIRD/ID); Daskalakis, Demetre (CDC/NCIRD/OD)
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Thanks all,
Ruffin

From: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Sent: Tuesday, May 28, 2024 5:57 PM
To: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>
Subject: Re: Health Hazard Evaluation - H5b Correction 5-16-2024

Thanks Demetre

James Stevens, Ph.D.
Associate Director for Laboratory Sciences
Influenza Division, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Rd - Mail stop H23-6
Atlanta, GA 30329-4027
Phone (404)-639-5008; Cell (b)(6)

From: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
Sent: Tuesday, May 28, 2024 5:56 PM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>; Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Thank you. I appreciate it.

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Tuesday, May 28, 2024 5:55 PM
To: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>

Cc: Booth, Ruffin (CDC/NCIRD/ID) <[ijw5@cdc.gov](mailto:iwj5@cdc.gov)>; Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Have pinged them with that detail. Thanks

From: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
Sent: Tuesday, May 28, 2024 5:07 PM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Booth, Ruffin (CDC/NCIRD/ID) <ijw5@cdc.gov>; Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

FDA is asking the document be submitted back to them this week.
John

From: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Sent: Tuesday, May 28, 2024 8:31 AM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Booth, Ruffin (CDC/NCIRD/ID) <ijw5@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi Demetre,
Did we hear back from IOD on the FDA correction paperwork?
We should try to submit this soon ☺
Many thanks
James

James Stevens, Ph.D.
Associate Director for Laboratory Sciences
Influenza Division, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Rd - Mail stop H23-6
Atlanta, GA 30329-4027
Phone (404)-639-5008; Cell: (404)-384-8795

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Thursday, May 23, 2024 12:09 PM
To: Booth, Ruffin (CDC/NCIRD/ID) <ijw5@cdc.gov>; Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Thanks! Communicating that to iOD

From: Booth, Ruffin (CDC/NCIRD/ID) <ijw5@cdc.gov>
Sent: Thursday, May 23, 2024 12:07 PM
To: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>; Daskalakis, Demetre (CDC/NCIRD/OD)
<yzq5@cdc.gov>

Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>

Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi James, Demetre,

Not all of the document will be public. I have attached an example of the information FDA pulls for the public facing website post. The CDC Director's information should not be public, per a conversation with the FDA Recall Coordinator Team Lead. What will be public is the Recall Contact at Recalling Firm. If desired, the current contact (me) can be changed.

Hope that helps,

Ruffin

Ruffin Booth, ASQ CMQ/OE, CQA, CSSBB; RAPS RAC

Quality Manager

Centers for Disease Control and Prevention, CDC

Influenza Division

Bldg 24, 7136, MS H24-7

Office: 404-639-1947

Cell: 404-263-2667

RBooth1@cdc.gov

From: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>

Sent: Thursday, May 23, 2024 11:22 AM

To: Booth, Ruffin (CDC/NCIRD/ID) <[ijw5@cdc.gov](mailto:iwj5@cdc.gov)>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>

Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <yvq5@cdc.gov>

Subject: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi Ruffin/John,

Demetre got a question back from IOD asking if the document will be a public document?

I'm assuming we do not want to provide the CDC Directors direct contact details if there is a chance it is. Can you please let us know. I'm falling on the side that if there is even a chance we should provide non-private contact information.

Thoughts? Is the document made public?

Thanks

James

James Stevens, Ph.D.

Associate Director for Laboratory Sciences (Acting)

National Center for Immunization and Respiratory Disease

NCIRD, Centers for Disease Control and Prevention

1600 Clifton Rd - Mail stop H23-6

Atlanta, GA 30329-4027

Phone (404)-639-5008; Cell: (404)-384-8795

From: Salerno, Reynolds (CDC/IOD/OLSS/CLSR)
Sent: Thu, 2 May 2024 20:38:27 +0000
To: Barnes, John R. (CDC/NCIRD/ID)
Subject: RE: Message for Dr. Cohen - IDT update and timeline details, per request

Wow, that was fast. Thanks, John. Really helpful for me.

From: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
Sent: Thursday, May 2, 2024 4:23 PM
To: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>
Subject: RE: Message for Dr. Cohen - IDT update and timeline details, per request

1. Where were each of the components synthesized and what post synthesis QA/QC was done (and by whom)? (b)(5)
(b)(5) QC/ QA done here basic concept ensure current kit components work to at least the same level as previous lots.
2. Was it clear to the manufacturer that all reagents would be utilized for clinical diagnostics and, if not, do they have different workflows for RUO vs clinical reagents? Yes we have two synthesis lines we outline in the contract and manufacture through with the company RUO and GMP. This was through the GMP line.
3. Were the "bulks" of the synthesized materials sent directly to CDC labs or to a manufacturer? CDC for QC testing then all the component tubes were filled and dried at the company, re-QC'd and then sent to ATCC for final kit assembly.
4. Who assembled the components into kits (IDT, CDC, or some other company)? ATCC assembled the kits but that is really just putting tubes in a box.... My Team still makes the PC
5. What "post fill" QA/QC was done and where was that done? See above. Done at company then QC'd here.
6. Were the acceptance criteria clear for all QA/QC steps and what were they? Yes, we have a standards that we test old lots vs new to ensure same criteria are kept lot to lot. Basically it has to do with the tolerance FDA allows us 2 CT swing (lower sensitivity only).
7. Is there any process in place for continued stability testing of produced lots (i.e., how do you know when kits should expire)? Yes, we have done extensive testing on this I had the team evaluate the performance of all of the tests for an additional year so we could extend our shelf life when I merged the teams in 2018.
8. What is the specific failure (i.e., false positive, invalid run or false negative) and what is the rate of failure? Is it within the set acceptance criteria? In the field we

(b)(5)

9. What causalities have been considered or investigated and what has been ruled in or out? What are the details of those (i.e., we know it is not an X issue because we did Y to investigate that)? It's a complicated story.

(b)(5)

(b)(5)

This kit was pretty new, not even a year old.

John

From: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>

Sent: Thursday, May 2, 2024 3:31 PM

To: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>

Subject: RE: Message for Dr. Cohen - IDT update and timeline details, per request

Just for you...

I hope you don't mind if I ask some QC-related questions. No rush on this, but I am curious.

1. Where were each of the components synthesized and what post synthesis QA/QC was done (and by whom)?
2. Was it clear to the manufacturer that all reagents would be utilized for clinical diagnostics and, if not, do they have different workflows for RUO vs clinical reagents?

3. Were the "bulks" of the synthesized materials sent directly to CDC labs or to a manufacturer?
4. Who assembled the components into kits (IDT, CDC, or some other company)?
5. What "post fill" QA/QC was done and where was that done?
6. Were the acceptance criteria clear for all QA/QC steps and what were they?
7. Is there any process in place for continued stability testing of produced lots (i.e., how do you know when kits should expire)?
8. What is the specific failure (i.e., false positive, invalid run or false negative) and what is the rate of failure? Is it within the set acceptance criteria?
9. What causalities have been considered or investigated and what has been ruled in or out? What are the details of those (i.e., we know it is not an X issue because we did Y to investigate that)?

An overriding question: Is the occurrence rate of the problem at a level that would be expected to be caught by industry standard QA/QC processes and does that rate increase with the age of the kit regardless of the expiration date?

Thanks,
Ren

From: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
Sent: Thursday, May 2, 2024 9:15 AM
To: Dugan, Vivien (CDC/NCIRD/ID) <lny1@cdc.gov>; Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>; Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>
Subject: RE: Message for Dr. Cohen - IDT update and timeline details, per request

-Nancy.

(b)(5)

John

From: Dugan, Vivien (CDC/NCIRD/ID) <lny1@cdc.gov>
Sent: Thursday, May 2, 2024 7:24 AM
To: Norton, Nancy (CDC/OCOO/OFR/OAS) <ftg8@cdc.gov>
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>
Subject: FW: Message for Dr. Cohen - IDT update and timeline details, per request

Nancy – FYSA
Demetre, John and I will discuss today.
Thanks,
Vivien

Vivien G. Dugan, PhD (she/her)
Director, Influenza Division
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, Atlanta, GA 30329
Office 404-718-5399, Mobile 678-488-5249
VDugan@cdc.gov

From: Cohen, Mandy K. (CDC/IOD) <jbc7@cdc.gov>
Sent: Wednesday, May 1, 2024 9:45 PM
To: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>; Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>; Dugan, Vivien (CDC/NCIRD/ID) <lny1@cdc.gov>
Subject: Re: Message for Dr. Cohen - IDT update and timeline details, per request

+ Ren and Viviane.

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From: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Sent: Wednesday, May 1, 2024 9:16:37 PM
To: Cohen, Mandy K. (CDC/IOD) <jbc7@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: Fwd: Message for Dr. Cohen - IDT update and timeline details, per request

From: Mills, Demaris (she / her) G < (b)(6) >
Sent: Wednesday, May 1, 2024 8:45:21 PM
To: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Subject: Message for Dr. Cohen - IDT update and timeline details, per request

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello Kate,

Thank you for arranging the connection between Dr Cohen and myself. I only have her cell phone but not email, so am sending this to you in the hopes that you can share along, as needed regarding the IDT components for the CDC Avian Flu assay.

Thanks for your help!

Demaris

Dear Dr. Cohen,

As a follow up to our discussion on Monday, I want to assure you that we have a team of senior scientists as well as my direct leaders engaged and working directly with your team, and I personally remain close.

Our first priority is to ensure that you have the products you need.

(b)(4)

As I shared with you,

(b)(5)

IDT has a strong collaborative relationship with the CDC. Jeff Zients and many others can attest to the impact of that partnership (b)(4)

(b)(4) and we are committed to providing whatever support you need with our strong technically capable staff.

Please do call any time.

Best regards,
Demaris

Demaris Mills
President

Integrated DNA Technologies, Inc.

m: (b)(6) | e: (b)(6)



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From: Kirby, Marie (CDC/NCIRD/ID)
Sent: Mon, 29 Apr 2024 20:11:15 +0000
To: Barr, John (CDC/NCEH/DLS); Jones, Deanna M. (CDC/NCEH/DLS); Jarrett, Jeff (CDC/NCEH/DLS); Ward, Cynthia (CDC/NCEH/DLS); Barnes, John R. (CDC/NCIRD/ID); Davis, Charles (Todd) (CDC/NCIRD/ID); Stevens, James (CDC/NCIRD/ID)
Cc: Dugan, Vivien (CDC/NCIRD/ID)
Subject: RE: Metal analysis in commercial oligo primers and probes
Attachments: Concentrations.PNG, IVD H5 rRT-PCR primer probe sequences.xlsx

Hello all,

Thanks again for your time and expertise on the call today – this is very much appreciated!
I am attaching some info for you surrounding the materials I will transfer to you.

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Kindly,

Marie

Marie Kirby, Ph.D.
Acting Team Lead – Genomics and Diagnostics Team
DDID/NCIRD/Influenza Division
Centers for Disease Control and Prevention
1600 Clifton Rd NE
Atlanta, GA 30329

Office: 404-718-7689

Cell: (b)(6)

Email: pbi0@cdc.gov

-----Original Appointment-----

From: Barr, John (CDC/NCEH/DLS) <jbb0@cdc.gov>

Sent: Tuesday, April 23, 2024 1:16 PM

To: Barr, John (CDC/NCEH/DLS); Jones, Deanna M. (CDC/NCEH/DLS); Jarrett, Jeff (CDC/NCEH/DLS); Ward, Cynthia (CDC/NCEH/DLS); Barnes, John R. (CDC/NCIRD/ID); Kirby, Marie (CDC/NCIRD/ID); Davis, Charles (Todd) (CDC/NCIRD/ID); Stevens, James (CDC/NCIRD/ID)

Cc: Dugan, Vivien (CDC/NCIRD/ID)

Subject: Metal analysis in commercial oligo primers and probes

When: Monday, April 29, 2024 3:00 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).

Where: Microsoft Teams Meeting

Please let me know if the meeting time works for everyone. This is one of the few times that appears to be open.

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Influenza A/H5 Subtyping Kit (VER 3) Contents: Catalog # FluIVD03-5
Box #1: Primers and Probes

Reagent Label	Part #	Description	Quantity / Tube	Reactions / Tube
InfA-F	MR-637	Influenza A Forward Primer	20 nmol	1000
InfA-R	MR-638	Influenza A Reverse Primer	20 nmol	1000
InfA-P	SO3285 or MR-431	Influenza A Probe (FAM)	5 nmol	1000
H5a-F	MR-409	Influenza H5a Forward Primer	30 nmol	1000
H5a-R	MR-433	Influenza H5a Reverse Primer	20 nmol	1000
H5a-P	MR-410	Influenza H5a Probe (FAM)	7.5 nmol	1000
H5b-F	MR-411	Influenza H5b Forward Primer	20 nmol	1000
H5b-R	MR-443	Influenza H5b Reverse Primer	20 nmol	1000
H5b-P	MR-434	Influenza H5b Probe (FAM)	5 nmol	1000
RP-F	SO3313	Human RNase P Forward Primer	20 nmol	1000
RP-R	SO3314	Human RNase P Reverse Primer	20 nmol	1000
RP-P	SO3315 or MR-432	Human RNase P Probe (FAM)	5 nmol	1000

From: Fresquez, Mark (CDC/NCEH/DLS)
Sent: Tue, 30 Apr 2024 17:15:47 +0000
To: Kirby, Marie (CDC/NCIRD/ID); Jarrett, Jeff (CDC/NCEH/DLS)
Cc: Dugan, Vivien (CDC/NCIRD/ID); Stevens, James (CDC/NCIRD/ID); Davis, Charles (Todd) (CDC/NCIRD/ID); Barnes, John R. (CDC/NCIRD/ID); Jones, Deanna M. (CDC/NCEH/DLS); Barr, John (CDC/NCEH/DLS); Ward, Cynthia (CDC/NCEH/DLS)
Subject: RE: Metal analysis in commercial oligo primers and probes

Hey Marie,
I will meet you at the Chamblee Campus visitor center. Talk to you soon.

Mark

Mark Fresquez, M.S.
Research Chemist
Centers for Disease Control and Prevention, CDC/NCEH/DLS/IRAT/EAL
4770 Buford Hwy.
Building: 103 Room: 1009
Atlanta, GA 30341-3717
770-488-0171
MFresquez@CDC.gov

From: Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>
Sent: Tuesday, April 30, 2024 12:05 PM
To: Jarrett, Jeff (CDC/NCEH/DLS) <jhj8@cdc.gov>; Fresquez, Mark (CDC/NCEH/DLS) <mwf6@cdc.gov>
Cc: Dugan, Vivien (CDC/NCIRD/ID) <lvy1@cdc.gov>; Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>;
Davis, Charles (Todd) (CDC/NCIRD/ID) <eou8@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID)
<fqz9@cdc.gov>; Jones, Deanna M. (CDC/NCEH/DLS) <hi4@cdc.gov>; Barr, John (CDC/NCEH/DLS)
<jbb0@cdc.gov>; Ward, Cynthia (CDC/NCEH/DLS) <dmo9@cdc.gov>
Subject: RE: Metal analysis in commercial oligo primers and probes

Hello Jeff and Mark,

I am happy to bring some kit materials.
I left Mark a voicemail – [@Fresquez, Mark \(CDC/NCEH/DLS\)](#) when you see this, if you can give me a call, we can plan where and when to meet for dropping off the materials.

I will bring you oligos from two kits.
The kits have a forward primer, reverse primer, and probe tube for each of the four targets (InfA, H5a, H5b, and RP).

The tubes where our initial analysis has indicated iron oxide is the H5b forward and H5b reverse primer tubes. We do not have the same contaminating peak observed in the H5b probe tube – so perhaps the analysis can begin there with comparing the materials across these three tubes?

Thank you,

Marie

Marie Kirby, Ph.D.
Acting Team Lead – Genomics and Diagnostics Team
DDID/NCIRD/Influenza Division
Centers for Disease Control and Prevention
1600 Clifton Rd NE
Atlanta, GA 30329
Office: 404-718-7689
Cell: 470-604-5078
Email: pbi0@cdc.gov

From: Jarrett, Jeff (CDC/NCEH/DLS) <jhj8@cdc.gov>
Sent: Tuesday, April 30, 2024 10:54 AM
To: Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>
Cc: Dugan, Vivien (CDC/NCIRD/ID) <lny1@cdc.gov>; Jarrett, Jeff (CDC/NCEH/DLS) <jhj8@cdc.gov>; Fresquez, Mark (CDC/NCEH/DLS) <mwf6@cdc.gov>; Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>; Davis, Charles (Todd) (CDC/NCIRD/ID) <euu8@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Jones, Deanna M. (CDC/NCEH/DLS) <hih4@cdc.gov>; Barr, John (CDC/NCEH/DLS) <bbb0@cdc.gov>; Ward, Cynthia (CDC/NCEH/DLS) <dmo9@cdc.gov>
Subject: Re: Metal analysis in commercial oligo primers and probes

Hi Marie,

Can you bring some of the kits to the Chamblee campus today?

Due to my schedule today it is probably best to have you connect with Mark Fresquez (404-664-7114), copied, to hand them off. Just give him a call to let him know where to meet you.

I see there are numerous tubes in each kit. Do you suspect the metal contaminant in a particular tube? Can you bring a kit that you think does not have the metal contaminant so we can have a comparison/control?

Jeff

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From: Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>
Sent: Tuesday, April 30, 2024 8:20 AM
To: Barr, John (CDC/NCEH/DLS) <bbb0@cdc.gov>; Jones, Deanna M. (CDC/NCEH/DLS) <hih4@cdc.gov>; Jarrett, Jeff (CDC/NCEH/DLS) <jhj8@cdc.gov>; Ward, Cynthia (CDC/NCEH/DLS) <dmo9@cdc.gov>;

Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Davis, Charles (Todd) (CDC/NCIRD/ID) <eou8@cdc.gov>; Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Cc: Dugan, Vivien (CDC/NCIRD/ID) <lny1@cdc.gov>
Subject: RE: Metal analysis in commercial oligo primers and probes

Hello,

Circling back around to provide sequence for our InfA and RP primers and probes and also provide the traces we received from the vendor for the H5b assay.

Kind regards,

Marie

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1600 Clifton Rd NE
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Office: 404-718-7689
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Email: pbi0@cdc.gov

From: Kirby, Marie (CDC/NCIRD/ID)
Sent: Monday, April 29, 2024 4:11 PM
To: Barr, John (CDC/NCEH/DLS) <jbb0@cdc.gov>; Jones, Deanna M. (CDC/NCEH/DLS) <hi4@cdc.gov>;
Jarrett, Jeff (CDC/NCEH/DLS) <ihj8@cdc.gov>; Ward, Cynthia (CDC/NCEH/DLS) <dmo9@cdc.gov>;
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To: Barr, John (CDC/NCEH/DLS); Jones, Deanna M. (CDC/NCEH/DLS); Jarrett, Jeff (CDC/NCEH/DLS); Ward, Cynthia (CDC/NCEH/DLS); Barnes, John R. (CDC/NCIRD/ID); Kirby, Marie (CDC/NCIRD/ID); Davis, Charles (Todd) (CDC/NCIRD/ID); Stevens, James (CDC/NCIRD/ID)
Cc: Dugan, Vivien (CDC/NCIRD/ID)
Subject: Metal analysis in commercial oligo primers and probes
When: Monday, April 29, 2024 3:00 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Microsoft Teams Meeting

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From: Kirby, Marie (CDC/NCIRD/ID)
Sent: Tue, 30 Apr 2024 12:20:34 +0000
To: Barr, John (CDC/NCEH/DLS); Jones, Deanna M. (CDC/NCEH/DLS); Jarrett, Jeff (CDC/NCEH/DLS); Ward, Cynthia (CDC/NCEH/DLS); Barnes, John R. (CDC/NCIRD/ID); Davis, Charles (Todd) (CDC/NCIRD/ID); Stevens, James (CDC/NCIRD/ID)
Cc: Dugan, Vivien (CDC/NCIRD/ID)
Subject: RE: Metal analysis in commercial oligo primers and probes
Attachments: IVD rRT-PCR primer probe sequences.xlsx, H5b-P_HPLC_220307.pdf, H5b-R_HPLC.pdf, H5b-F_HPLC_220307_Remade 429283973.pdf

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Cell: 470-604-5078
Email: pbi0@cdc.gov

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From: Jarrett, Jeff (CDC/NCEH/DLS)
Sent: Mon, 29 Apr 2024 20:42:30 +0000
To: Kirby, Marie (CDC/NCIRD/ID)
Cc: Dugan, Vivien (CDC/NCIRD/ID); Ward, Cynthia (CDC/NCEH/DLS); Stevens, James (CDC/NCIRD/ID); Davis, Charles (Todd) (CDC/NCIRD/ID); Barnes, John R. (CDC/NCIRD/ID); Jones, Deanna M. (CDC/NCEH/DLS); Jarrett, Jeff (CDC/NCEH/DLS); Barr, John (CDC/NCEH/DLS)
Subject: RE: Metal analysis in commercial oligo primers and probes

Hi Marie,

Thank you for this information. Cynthia is going to speak with our Branch Chief about this tomorrow morning and we'll reach back out to you.

Best regards,

Jeff

Jeff Jarrett, M.S.

Chief, Elemental Analysis Lab
Inorganic and Radiation Analytical Toxicology Branch, CDC
4770 Buford Hwy., Mail Stop F-18, Atlanta, GA 30341
770-488-7906 (work)
JJarrett@cdc.gov

From: Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>
Sent: Monday, April 29, 2024 4:11 PM
To: Barr, John (CDC/NCEH/DLS) <jjb0@cdc.gov>; Jones, Deanna M. (CDC/NCEH/DLS) <hi4@cdc.gov>;
Jarrett, Jeff (CDC/NCEH/DLS) <jhh8@cdc.gov>; Ward, Cynthia (CDC/NCEH/DLS) <dmo9@cdc.gov>;
Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Davis, Charles (Todd) (CDC/NCIRD/ID)
<eou8@cdc.gov>; Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Cc: Dugan, Vivien (CDC/NCIRD/ID) <lny1@cdc.gov>
Subject: RE: Metal analysis in commercial oligo primers and probes

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DDID/NCIRD/Influenza Division
Centers for Disease Control and Prevention
1600 Clifton Rd NE
Atlanta, GA 30329
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From: Jarrett, Jeff (CDC/NCEH/DLS)
Sent: Thu, 16 May 2024 15:56:57 +0000
To: Kirby, Marie (CDC/NCIRD/ID)
Cc: Barnes, John R. (CDC/NCIRD/ID); Michaud, Jonathan (CDC/NCEH/DLS) (CTR); Valentin-Blasini, Liza (CDC/NCEH/DLS); Fresquez, Mark (CDC/NCEH/DLS); Ward, Cynthia (CDC/NCEH/DLS)
Subject: RE: Metal analysis

Will do. Safe traveling.

Jeff

From: Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>
Sent: Thursday, May 16, 2024 10:43 AM
To: Jarrett, Jeff (CDC/NCEH/DLS) <jhh8@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Michaud, Jonathan (CDC/NCEH/DLS) (CTR) <pjt5@cdc.gov>; Valentin-Blasini, Liza (CDC/NCEH/DLS) <lbv5@cdc.gov>; Fresquez, Mark (CDC/NCEH/DLS) <mwf6@cdc.gov>; Ward, Cynthia (CDC/NCEH/DLS) <dmo9@cdc.gov>; Jarrett, Jeff (CDC/NCEH/DLS) <jhh8@cdc.gov>
Subject: Re: Metal analysis

Dear Jeff, Mark, and JD

Thank you so much for sending this analysis and for all of the hard work and effort you have put in over the past few weeks. We very much appreciate your expertise. I am traveling this week, so please hold on to the residual materials and I will circle back around to you next week.

Best regards

Marie

From: Jarrett, Jeff (CDC/NCEH/DLS) <jhh8@cdc.gov>
Sent: Wednesday, May 15, 2024 8:34 AM
To: Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Michaud, Jonathan (CDC/NCEH/DLS) (CTR) <pjt5@cdc.gov>; Valentin-Blasini, Liza (CDC/NCEH/DLS) <lbv5@cdc.gov>; Fresquez, Mark (CDC/NCEH/DLS) <mwf6@cdc.gov>; Ward, Cynthia (CDC/NCEH/DLS) <dmo9@cdc.gov>; Jarrett, Jeff (CDC/NCEH/DLS) <jhh8@cdc.gov>
Subject: RE: Metal analysis

Hi Marie,

Here is a summary of our findings.

(b)(5)

Keep in mind that the ICP-MS methods we used were not fully validated and were for exploratory research only. We reached these conclusions (b)(5) (b)(5)

(b)(5)

Many thanks to Mark and JD for their work in the lab on this.

I'd be happy to have a call to discuss the details. Let us know what you'd like us to do with the remaining materials.

Jeff

From: Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>
Sent: Friday, May 10, 2024 8:33 AM
To: Jarrett, Jeff (CDC/NCEH/DLS) <jhj8@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Michaud, Jonathan (CDC/NCEH/DLS) (CTR) <pit5@cdc.gov>; Valentin-Blasini, Liza (CDC/NCEH/DLS) <lbv5@cdc.gov>; Fresquez, Mark (CDC/NCEH/DLS) <mwf6@cdc.gov>; Ward, Cynthia (CDC/NCEH/DLS) <dmo9@cdc.gov>
Subject: RE: Metal analysis

Hello Jeff,

I just wanted to check in to see how things were going from your side?

Thanks so much,

Marie

Marie Kirby, Ph.D.
Acting Team Lead – Genomics and Diagnostics Team
DDID/NCIRD/Influenza Division
Centers for Disease Control and Prevention
1600 Clifton Rd NE
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Cell: 470-604-5078
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From: Jarrett, Jeff (CDC/NCEH/DLS) <jhj8@cdc.gov>
Sent: Tuesday, May 7, 2024 11:00 AM
To: Kirby, Marie (CDC/NCIRD/ID) <pbj0@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Michaud, Jonathan (CDC/NCEH/DLS) (CTR) <pit5@cdc.gov>; Valentin-Blasini, Liza (CDC/NCEH/DLS) <lbv5@cdc.gov>; Fresquez, Mark (CDC/NCEH/DLS) <mwf6@cdc.gov>; Ward, Cynthia (CDC/NCEH/DLS) <dmo9@cdc.gov>; Jarrett, Jeff (CDC/NCEH/DLS) <jhj8@cdc.gov>
Subject: RE: Metal analysis

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From: Kirby, Marie (CDC/NCIRD/ID)
Sent: Tue, 7 May 2024 15:03:00 +0000
To: Jarrett, Jeff (CDC/NCEH/DLS)
Cc: Barnes, John R. (CDC/NCIRD/ID); Michaud, Jonathan (CDC/NCEH/DLS) (CTR); Valentin-Blasini, Liza (CDC/NCEH/DLS); Fresquez, Mark (CDC/NCEH/DLS); Ward, Cynthia (CDC/NCEH/DLS)
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Hi Jeff,

I will head that way shortly – will call you when I arrive. Should be around 11:45 or so.

Thanks

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From: Jarrett, Jeff (CDC/NCEH/DLS)
Sent: Fri, 10 May 2024 12:33:58 +0000
To: Kirby, Marie (CDC/NCIRD/ID)
Cc: Barnes, John R. (CDC/NCIRD/ID); Michaud, Jonathan (CDC/NCEH/DLS) (CTR); Valentin-Blasini, Liza (CDC/NCEH/DLS); Fresquez, Mark (CDC/NCEH/DLS); Ward, Cynthia (CDC/NCEH/DLS)
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Hey Marie,

JD and Mark completed the analysis yesterday, and I'll be reviewing the data today.

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Mark and JD did a second round of tests of the H5b vials (probe, forward, and reverse) on May 2. This time all signals (b)(5) The forward material continued to have the

(b) (5)

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From: Barnes, John R. (CDC/NCIRD/ID)
Sent: Wed, 15 May 2024 18:04:04 +0000
To: Stevens, James (CDC/NCIRD/ID); Davis, Charles (Todd) (CDC/NCIRD/ID); Dugan, Vivien (CDC/NCIRD/ID); Shimabukuro, Tom (CDC/NCIRD/ID)
Cc: Kirby, Marie (CDC/NCIRD/ID)
Subject: RE: Metal analysis

+ Tom as I accidentally omitted him from the first email

Yes, that is correct.

(b)(5)

John

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Sent: Wednesday, May 15, 2024 1:57 PM
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Subject: Re: Metal analysis

and nickel is all primers at the same level?

James Stevens, Ph.D.

Associate Director for Laboratory Sciences (Acting)

National Center for Immunization and Respiratory Disease

NCIRD, Centers for Disease Control and Prevention

1600 Clifton Rd - Mail stop H23-6

Atlanta, GA 30329-4027

Phone (404)-639-5008; Cell: (404)-384-8795

From: Barnes, John R. (CDC/NCIRD/ID) <fqz9@cdc.gov>
Sent: Wednesday, May 15, 2024 1:21 PM
To: Davis, Charles (Todd) (CDC/NCIRD/ID) <eou8@cdc.gov>; Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>; Dugan, Vivien (CDC/NCIRD/ID) <lny1@cdc.gov>
Cc: Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>
Subject: FW: Metal analysis

FYA.

(b)(5)

John

From: Jarrett, Jeff (CDC/NCEH/DLS) <jhj8@cdc.gov>
Sent: Wednesday, May 15, 2024 10:35 AM
To: Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Michaud, Jonathan (CDC/NCEH/DLS) (CTR) <pit5@cdc.gov>; Valentin-Blasini, Liza (CDC/NCEH/DLS) <lbv5@cdc.gov>; Fresquez, Mark (CDC/NCEH/DLS) <mwf6@cdc.gov>; Ward, Cynthia (CDC/NCEH/DLS) <dmo9@cdc.gov>; Jarrett, Jeff (CDC/NCEH/DLS) <jhj8@cdc.gov>
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Hi Marie,

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Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Michaud, Jonathan (CDC/NCEH/DLS) (CTR) <pit5@cdc.gov>; Valentin-Blasini, Liza (CDC/NCEH/DLS) <lbv5@cdc.gov>; Fresquez, Mark (CDC/NCEH/DLS) <mwf6@cdc.gov>; Ward, Cynthia (CDC/NCEH/DLS) <dmo9@cdc.gov>
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Hello Jeff,

I just wanted to check in to see how things were going from your side?

Thanks so much,

Marie

Marie Kirby, Ph.D.
Acting Team Lead – Genomics and Diagnostics Team
DDID/NCIRD/Influenza Division
Centers for Disease Control and Prevention
1600 Clifton Rd NE
Atlanta, GA 30329
Office: 404-718-7689
Cell: 470-604-5078
Email: pbi0@cdc.gov

From: Jarrett, Jeff (CDC/NCEH/DLS) <bj8@cdc.gov>
Sent: Tuesday, May 7, 2024 11:00 AM
To: Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Michaud, Jonathan (CDC/NCEH/DLS) (CTR) <pjt5@cdc.gov>; Valentin-Blasini, Liza (CDC/NCEH/DLS) <lbv5@cdc.gov>; Fresquez, Mark (CDC/NCEH/DLS) <mwf6@cdc.gov>; Ward, Cynthia (CDC/NCEH/DLS) <dmo9@cdc.gov>; Jarrett, Jeff (CDC/NCEH/DLS) <bj8@cdc.gov>
Subject: RE: Metal analysis

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From: Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>
Sent: Tuesday, May 7, 2024 10:53 AM
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Subject: RE: Metal analysis

Hi Jeff,

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I am happy to bring additional sets of H5b – Just let me know what time to meet you all and I can meet you at the visitors center at Chamblee again.

Thanks

Marie

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1600 Clifton Rd NE
Atlanta, GA 30329
Office: 404-718-7689
Cell: 470-604-5078
Email: pbj0@cdc.gov

From: Jarrett, Jeff (CDC/NCEH/DLS) <jhi8@cdc.gov>
Sent: Tuesday, May 7, 2024 10:45 AM
To: Kirby, Marie (CDC/NCIRD/ID) <pbj0@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Michaud, Jonathan (CDC/NCEH/DLS) (CTR) <pjt5@cdc.gov>; Valentin-Blasini, Liza (CDC/NCEH/DLS) <lbv5@cdc.gov>; Fresquez, Mark (CDC/NCEH/DLS) <mwf6@cdc.gov>; Ward, Cynthia (CDC/NCEH/DLS) <dmo9@cdc.gov>; Jarrett, Jeff (CDC/NCEH/DLS) <jhi8@cdc.gov>
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Hey Marie,

(b)(5)

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Best regards,

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From: Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>
Sent: Monday, May 6, 2024 3:11 PM
To: Jarrett, Jeff (CDC/NCEH/DLS) <hhj8@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Michaud, Jonathan (CDC/NCEH/DLS) (CTR) <pit5@cdc.gov>; Valentin-Blasini, Liza (CDC/NCEH/DLS) <lbv5@cdc.gov>; Fresquez, Mark (CDC/NCEH/DLS) <mwf6@cdc.gov>; Ward, Cynthia (CDC/NCEH/DLS) <dmo9@cdc.gov>
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Thank you so much for your expertise and support – we truly appreciate it!

Marie

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Atlanta, GA 30329
Office: 404-718-7689
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Email: pbi0@cdc.gov

From: Jarrett, Jeff (CDC/NCEH/DLS) <hhj8@cdc.gov>
Sent: Friday, May 3, 2024 8:23 AM
To: Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Michaud, Jonathan (CDC/NCEH/DLS) (CTR) <pit5@cdc.gov>; Valentin-Blasini, Liza (CDC/NCEH/DLS) <lbv5@cdc.gov>; Fresquez, Mark (CDC/NCEH/DLS) <mwf6@cdc.gov>; Jarrett, Jeff (CDC/NCEH/DLS) <hhj8@cdc.gov>; Ward, Cynthia (CDC/NCEH/DLS) <dmo9@cdc.gov>
Subject: RE: Metal analysis

Hi Marie,

I can give you a little more information about our progress so far.

(b)(5)

(b)(5)

I'm looping in our branch chief, Liza, and deputy, Cynthia, for awareness.

We'll be in touch,

Jeff

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Subject: RE: Metal analysis

Hey Marie,

We have initial results completed and are tabulating the data. We will go over the data today and reach out after that. Thanks, we'll be in touch soon!

Mark

Mark Fresquez, M.S.

Research Chemist

Centers for Disease Control and Prevention, CDC/NCEH/DLS/IRAT/EAL

4770 Buford Hwy.

Building: 103 Room: 1009

Atlanta, GA 30341-3717

770-488-0171

MFresquez@CDC.gov

From: Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>
Sent: Thursday, May 2, 2024 8:34 PM
To: Fresquez, Mark (CDC/NCEH/DLS) <mwf6@cdc.gov>; Jarrett, Jeff (CDC/NCEH/DLS) <jhj8@cdc.gov>
Cc: Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>
Subject: Metal analysis

Hello Mark and Jeff,

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We appreciate your support and assistance!

Kind regards,

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From: Barnes, John R. (CDC/NCIRD/ID)
Sent: Wed, 15 May 2024 15:07:59 +0000
To: Jarrett, Jeff (CDC/NCEH/DLS); Kirby, Marie (CDC/NCIRD/ID)
Cc: Michaud, Jonathan (CDC/NCEH/DLS) (CTR); Valentin-Blasini, Liza (CDC/NCEH/DLS); Fresquez, Mark (CDC/NCEH/DLS); Ward, Cynthia (CDC/NCEH/DLS)
Subject: RE: Metal analysis

Jeff,

Thanks so much! This is really great. We greatly appreciate it.

John

From: Jarrett, Jeff (CDC/NCEH/DLS) <jhj8@cdc.gov>
Sent: Wednesday, May 15, 2024 10:35 AM
To: Kirby, Marie (CDC/NCIRD/ID) <ppb10@cdc.gov>
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Research Chemist
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Building: 103 Room: 1009
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770-488-0171
MFrdezquez@CDC.gov

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Centers for Disease Control and Prevention
1600 Clifton Rd NE
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Office: 404-718-7689
Cell: 470-604-5078
Email: pbi0@cdc.gov

From: Boswell, Haley C. (CDC/NCIRD/ID)
Sent: Fri, 5 Jul 2024 16:41:54 +0000
To: Stevens, James (CDC/NCIRD/ID); Barnes, John R. (CDC/NCEZID/DIDRI/OAMD);
Davis, Charles (Todd) (CDC/NCIRD/ID); Kirby, Marie (CDC/NCIRD/ID); Shimabukuro, Tom
(CDC/NCIRD/ID); Gogstad, Eric (CDC/NCIRD/ID)
Cc: Culp, Lindsay A. (CDC/NCIRD/ID); Dugan, Vivien (CDC/NCIRD/ID)
Subject: RE: Responses to tough Q&A for congressional briefing - COB, Friday 7/5

Thanks all, this is helpful. Will ping you in the doc if any additional follow-up is needed.

From: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Sent: Friday, July 5, 2024 10:56 AM
To: Barnes, John R. (CDC/NCEZID/DIDRI/OAMD) <fzq9@cdc.gov>; Davis, Charles (Todd) (CDC/NCIRD/ID)
<eou8@cdc.gov>; Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>; Shimabukuro, Tom (CDC/NCIRD/ID)
<ayv6@cdc.gov>; Gogstad, Eric (CDC/NCIRD/ID) <elg5@cdc.gov>
Cc: Culp, Lindsay A. (CDC/NCIRD/ID) <lc9@cdc.gov>; Boswell, Haley C. (CDC/NCIRD/ID) <gfi9@cdc.gov>;
Dugan, Vivien (CDC/NCIRD/ID) <lny1@cdc.gov>
Subject: RE: Responses to tough Q&A for congressional briefing - COB, Friday 7/5

Some questions/edits on the initial questions.

(b)(5)

Is

Qiagen contract not public knowledge?

James Stevens, Ph.D.
Associate Director for Laboratory Sciences
Influenza Division, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Rd - Mail stop H23-6
Atlanta, GA 30329-4027
Phone (404)-639-5008; Cell: (404)-384-8795

From: Barnes, John R. (CDC/NCEZID/DIDRI/OAMD) <fzq9@cdc.gov>
Sent: Friday, July 5, 2024 10:30 AM
To: Davis, Charles (Todd) (CDC/NCIRD/ID) <eou8@cdc.gov>; Stevens, James (CDC/NCIRD/ID)
<fwb4@cdc.gov>; Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>; Shimabukuro, Tom (CDC/NCIRD/ID)
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Dugan, Vivien (CDC/NCIRD/ID) <lny1@cdc.gov>
Subject: RE: Responses to tough Q&A for congressional briefing - COB, Friday 7/5
Importance: High

All,

I have started some answers these are consistent with what is going to be in our report back to FDA for the recall. (Haley I saw your second email. We really aren't working with the company anymore so we should steer clear of that.) Please edit, these are tricky.

John

1. Have you resolved the issue with the H5N1 assay? What's the status update?

(b)(5)

2. What is CDC doing to determine the source of the contamination?

(b)(5)

3. Origins of the contaminated component?

(b)(5)

4. How can CDC be sure this test is working to identify positive cases?

(b)(5)

5. What are you doing to fix this?

(b)(5)

6. Who is the new manufacturer of the test? How and why were they selected?

(b)(5)

7. Will you be clawing back some of the money you paid for the tests?

(b)(5)

8. If/when we need additional testing capacity in high throughput commercial labs, is CDC ready?
What are you doing to prepare for that?

(b)(5)

From: Boswell, Haley C. (CDC/NCIRD/ID) <gfi9@cdc.gov>

Sent: Thursday, July 4, 2024 11:47 PM

To: Barnes, John R. (CDC/NCEZID/DIDRI/OAMD) <fzq9@cdc.gov>; Davis, Charles (Todd) (CDC/NCIRD/ID)

<eou8@cdc.gov>

Subject: Responses to tough Q&A for congressional briefing - COB, Friday 7/5

Hi John and Todd,

We are prepping Vivien for a congressional briefing next week with some tough Q&A, since it will not be a friendly crowd. Can you please provide answers to the questions below related to the H5b primers/probe? They can be succinct, high-level bullets.

1. Have you resolved the issue with the H5N1 assay? What's the status update?
2. What is CDC doing to determine the source of the contamination?
3. Origins of the contaminated component?
4. How can CDC be sure this test is working to identify positive cases?
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Haley

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To: Davis, Charles (Todd) (CDC/NCIRD/ID); Stevens, James (CDC/NCIRD/ID); Kirby, Marie (CDC/NCIRD/ID); Shimabukuro, Tom (CDC/NCIRD/ID); Gogstad, Eric (CDC/NCIRD/ID)
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Importance: High

All,

I have started some answers these are consistent with what is going to be in our report back to FDA for the recall. (Haley I saw your second email. We really aren't working with the company anymore so we should steer clear of that.) Please edit, these are tricky.

John

1. Have you resolved the issue with the H5N1 assay? What's the status update?

(b)(5)

2. What is CDC doing to determine the source of the contamination?

(b)(5)

3. Origins of the contaminated component?

(b)(5)

4. How can CDC be sure this test is working to identify positive cases?

(b)(5)

5. What are you doing to fix this?

(b)(5)

6. Who is the new manufacturer of the test? How and why were they selected?

(b)(5)

7. Will you be clawing back some of the money you paid for the tests?

(b)(5)

8. If/when we need additional testing capacity in high throughput commercial labs, is CDC ready?
What are you doing to prepare for that?

(b)(5)

From: Boswell, Haley C. (CDC/NCIRD/ID) <gfi9@cdc.gov>

Sent: Thursday, July 4, 2024 11:47 PM

To: Barnes, John R. (CDC/NCEZID/DIDRI/OAMD) <fqz9@cdc.gov>; Davis, Charles (Todd) (CDC/NCIRD/ID) <eou8@cdc.gov>

Subject: Responses to tough Q&A for congressional briefing - COB, Friday 7/5

Hi John and Todd,

We are prepping Vivien for a congressional briefing next week with some tough Q&A, since it will not be a friendly crowd. Can you please provide answers to the questions below related to the H5b primers/probe? They can be succinct, high-level bullets.

1. Have you resolved the issue with the H5N1 assay? What's the status update?
2. What is CDC doing to determine the source of the contamination?
3. Origins of the contaminated component?
4. How can CDC be sure this test is working to identify positive cases?
5. What are you doing to fix this?
6. Who is the new manufacturer of the test? How and why were they selected?
7. Will you be clawing back some of the money you paid for the tests?
8. If/when we need additional testing capacity in high throughput commercial labs, is CDC ready?
What are you doing to prepare for that?

Thanks!

Haley

From: Booth, Ruffin (CDC/NCIRD/ID)
Sent: Fri, 17 May 2024 11:06:00 +0000
To: Uyeki, Timothy M. (CDC/NCIRD/ID)
Cc: Barnes, John R. (CDC/NCIRD/ID); Kirby, Marie (CDC/NCIRD/ID); Ivey, Melissa (CDC/IOD/OLSS/OD); Goodrich, April (CDC/NCIRD/ID)
Subject: FW: Health Hazard Evaluation - H5b Correction 5-16-2024
Attachments: Health Hazard Evaluation - H5b Correction 5-16-2024_MLI.docx

Good morning Tim,

We are preparing a Health Hazard Evaluation for submission to FDA with the recall notice. Can you look this over from a medical perspective to make sure we do not say something that is incorrect?

Thank you very much!

Ruffin

From: Ivey, Melissa (CDC/IOD/OLSS/OD) <mtq3@cdc.gov>
Sent: Thursday, May 16, 2024 3:43 PM
To: Booth, Ruffin (CDC/NCIRD/ID) <iwj5@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID) <fqz9@cdc.gov>; Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>; Goodrich, April (CDC/NCIRD/ID) <xbn6@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Here are my edits. Take them or leave them! Overall I think it looks good.

==

Melissa (Mel) Ivey, M.S., CQPA

Acting Lead, Regulatory Affairs Activity (RAA)
Quality Manager, Office of Laboratory Science (OLSci)
Office of Laboratory Science and Safety (OLSS)
Centers for Disease Control & Prevention
M-F 7:30a-4:00p
P: 404-639-1673 | C: 919-889-9514 | E: mtq3@cdc.gov

OLSS is an ISO 9001 certified organization

From: Booth, Ruffin (CDC/NCIRD/ID) <iwj5@cdc.gov>
Sent: Thursday, May 16, 2024 3:22 PM
To: Barnes, John R. (CDC/NCIRD/ID) <fqz9@cdc.gov>; Kirby, Marie (CDC/NCIRD/ID) <pbi0@cdc.gov>; Ivey, Melissa (CDC/IOD/OLSS/OD) <mtq3@cdc.gov>; Goodrich, April (CDC/NCIRD/ID) <xbn6@cdc.gov>
Subject: Health Hazard Evaluation - H5b Correction 5-16-2024

Time for another review.

Thanks!

From: Limbago, Brandi (CDC/NCIRD/OD)
Sent: Fri, 17 May 2024 22:01:10 +0000
To: Daskalakis, Demetre (CDC/NCIRD/OD)
Subject: FW: Health Hazard Evaluation - H5b Correction 5-16-2024
Attachments: FDA-5072 11-30-2023 CDC FluiVD03-11 Lot 220307 Correction.pdf, Health Hazard Evaluation - H5b Correction Lot 220307.docx

Ready to share through IOD

From: Stevens, James (CDC/NCIRD/ID) <fwb4@cdc.gov>
Sent: Friday, May 17, 2024 4:33 PM
To: Limbago, Brandi (CDC/NCIRD/OD) <bb17@cdc.gov>; Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Booth, Ruffin (CDC/NCIRD/ID) <ihj5@cdc.gov>; Barnes, John R. (CDC/NCIRD/ID) <fzq9@cdc.gov>; Dugan, Vivien (CDC/NCIRD/ID) <lny1@cdc.gov>; Kuehl, Debra B. (CDC/NCIRD/OD) <dpk6@cdc.gov>
Subject: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi Demetre and Brandi,

For the H5 kit primer issue, attached are copies of the Health Hazard Evaluation, and the FDA Recall Notice that needs to be sent to FDA.

Please take a look let us know if you have any questions/edits. Once Center approves these, we will then need to send this up to OID.

Dr. Cohen is the listed 'Top Firm' official in the recall notice form and OID will need edit and clear this section and provide appropriate contact information for Dr. Cohen (email/phone).

Many thanks for your help

James

James Stevens, Ph.D.

Associate Director for Laboratory Sciences (Acting)

National Center for Immunization and Respiratory Disease

NCIRD, Centers for Disease Control and Prevention

1600 Clifton Rd - Mail stop H23-6

Atlanta, GA 30329-4027

Phone (404)-639-5008; Cell: (404)-384-8795

From: Daskalakis, Demetre (CDC/NCIRD/OD)
Sent: Thu, 23 May 2024 15:11:45 +0000
To: Stevens, James (CDC/NCIRD/ID)
Subject: FW: Health Hazard Evaluation - H5b Correction 5-16-2024

See question from COS. I think the answer is yes, but confirming

From: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Sent: Thursday, May 23, 2024 11:10 AM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Got it – and is this a public document?

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Thursday, May 23, 2024 9:40 AM
To: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Yes. Also happy to take any additional feedback. I know it's a technical communication, but wanted to make sure I got any feedback.

From: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Sent: Thursday, May 23, 2024 9:19 AM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: RE: Health Hazard Evaluation - H5b Correction 5-16-2024

Hi – want to make sure I understand the ask here – you need the appropriate phone and email address for the director? Is there something else that we would need to do for this?

The phone should be CDC main line: 800-232-4636
Email address is: director@cdc.gov

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Wednesday, May 22, 2024 1:32 PM
To: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR) <yyw2@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: Health Hazard Evaluation - H5b Correction 5-16-2024

Kate-
See attached and below- We have to send this over to the FDA after you all have reviewed and added the desired information for MKC.

For the H5 kit primer issue, attached are copies of the Health Hazard Evaluation, and the FDA Recall Notice that needs to be sent to FDA.

Dr. Cohen is the listed 'Top Firm' official in the recall notice form and OID will need edit and clear this section and provide appropriate contact information for Dr. Cohen.

Thanks

Demetre

From: Booth, Ruffin (CDC/NCIRD/ID)
Sent: Thu, 27 Jun 2024 18:06:00 +0000
To: Kirby, Marie (CDC/NCIRD/ID); Ivey, Melissa (CDC/IOD/OLSS/OD); Barnes, John R. (CDC/NCIRD/ID)
Cc: Goodrich, April (CDC/NCIRD/ID)
Subject: FW: RES# 94739 - Centers For Disease Control and Prevention - Classification Email

Just received.

(b)(5)

(b)(5)
FYI,
Ruffin

From: Influenza Quality Team (CDC) <influenzaquality@cdc.gov>
Sent: Thursday, June 27, 2024 2:00 PM
To: Trivedi, Dipti (CDC/NCIRD/ID) <oow7@cdc.gov>; Goodrich, April (CDC/NCIRD/ID) <xbn6@cdc.gov>;
Booth, Ruffin (CDC/NCIRD/ID) <[ijh5@cdc.gov](mailto:iwj5@cdc.gov)>; Broeker, Robin (CDC/NCIRD/ID) <euj1@cdc.gov>
Subject: FW: RES# 94739 - Centers For Disease Control and Prevention - Classification Email

From: FDA_Recalls@fda.hhs.gov <FDA_Recalls@fda.hhs.gov>
Sent: Thursday, June 27, 2024 2:00:16 PM (UTC-05:00) Eastern Time (US & Canada)
To: Influenza Quality Team (CDC) <influenzaquality@cdc.gov>; Dr. Mandy K. Cohen (CDC) <director@cdc.gov>
Cc: oradevices2recalls@fda.hhs.gov <oradevices2recalls@fda.hhs.gov>
Subject: RES# 94739 - Centers For Disease Control and Prevention - Classification Email

We have reviewed your action and have determined that it meets the formal definition of a Recall. As previously advised, this recall will be reported in the FDA Enforcement Report.

The FDA has classified each product in the recall as a Class I, II, or III. Recall classification means the numerical designation assigned by FDA to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled. The table at the bottom of this email tells you the recall classification, the definitions are as follows:

- Class I recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.
- Class II recall: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III recall: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

This is a reminder that you should follow FDA's recall regulations: Enforcement Policy-Recalls (including Product Corrections) -- Guidelines on Policy, Procedures and Industry Responsibilities and FDA's Methods for Conducting Recall Effectiveness Checks in conducting your recall. The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. Unless you have discussed otherwise with FDA, you should conduct Level A (100%) effectiveness checks at direct accounts. If your recall

strategy includes having downstream customers further notify their own accounts you should assure that these customers are following your recall instructions.

Additional resources can be found on the [FDA.gov](#) website.

This is a reminder that you should also submit recall [status reports](#) to your Division recall contact, noted below at monthly intervals, unless otherwise instructed. Submit a written request for recall termination to your Division recall contact once all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. FDA will notify you in writing when we concur with your termination request.

Your cooperation in this matter is important for the protection of the general public. In the event FDA is not able to assess the progress and effectiveness of the recall, and consistent with our public health responsibilities, FDA may take further action, as appropriate, to remedy the underlying violation to address a product found to be in violation of the law, including, but not limited to, public warning to consumers, health practitioners, etc., seizure, or injunction.

Please refer to RES event number 94739 when corresponding with FDA and address all correspondence for this recall to oradevices2recalls@fda.hhs.gov. FDA will remain in contact with your firm until this matter is resolved.

The information below will appear in the [FDA Enforcement Report](#). As the recall progresses the status and the date terminated will be updated and these changes will be reflected in the FDA Enforcement Report.

- Event ID: 94739

- Recall Number: Z-2220-2024
- Product Description: CDC, Influenza A/H5 Subtyping Kit, Model/Catalog Number: FluiVD03-11
- Code Information: Lot Code: Catalog # FluiVD03-11, lot 220307
- Reason for Recall: The H5b component may fail to amplify, resulting in an inconclusive result.
- Product Quantity: 191 units
- Classification: Class II
- Voluntary/Mandated: Firm Initiated
- Product Type: Devices
- Initial Firm Notification of Consignee or Public: Letter
- Status: Ongoing
- Distribution Pattern: US Nationwide distribution.
- Recalling Firm: Centers For Disease Control and Prevention
- Recall Initiation Date: 04/26/2024
- Center Classification Date: 06/27/2024
- Date Terminated:

From: Stevens, James (CDC/NCIRD/ID)
Sent: Fri, 17 May 2024 20:33:12 +0000
To: Limbago, Brandi (CDC/NCIRD/OD); Daskalakis, Demetre (CDC/NCIRD/OD)
Cc: Booth, Ruffin (CDC/NCIRD/ID); Barnes, John R. (CDC/NCIRD/ID); Dugan, Vivien (CDC/NCIRD/ID); Kuehl, Debra B. (CDC/NCIRD/OD)
Subject: Health Hazard Evaluation - H5b Correction 5-16-2024
Attachments: FDA-5072 11-30-2023 CDC FluIVD03-11 Lot 220307 Correction.pdf, Health Hazard Evaluation - H5b Correction Lot 220307.docx

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Many thanks for your help
James

James Stevens, Ph.D.
Associate Director for Laboratory Sciences (Acting)
National Center for Immunization and Respiratory Disease
NCIRD, Centers for Disease Control and Prevention
1600 Clifton Rd - Mail stop H23-6
Atlanta, GA 30329-4027
Phone (404)-639-5008; Cell: (404)-384-8795

From: Daskalakis, Demetre (CDC/NCIRD/OD)
Sent: Wed, 22 May 2024 17:32:07 +0000
To: Wolff, Kate L. (CDC/IOD/OCS)
Cc: Salerno, Reynolds (CDC/IOD/OLSS/CLSR); Nirav Shah (CDC/IOD) (yyy8@cdc.gov)
Subject: Health Hazard Evaluation - H5b Correction 5-16-2024
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Kate-

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Thanks

Demetre