Visual Aid for Cartridge Inspection

Contents

Visual Aid for Cartridge Inspection

1 Purpose

This document is for use with D8148, D16199 and D12547. It provides a visual aid for defects found on completed cartridges.

2 Scope

This document pertains to visual inspection that occurs during Manufacturing and In-Process Testing.

3 Reference Documents

D8148 Reagents On Board Assembly Line (ROBAL) Operating Instructions

D16199 ROBAL II Operating Instructions

D36739 NFC Standalone Operating Instructions

D36415 USPS Standalone Operating Instructions

D12547 ROBAL Product Testing Procedure

4 Definitions

Major Visual Defect- The defect has a likelihood to cause a major functional failure in the cartridge, Erroneous-But-Believable (EBB) result or misinformation to the end users.

Minor Visual Defect- The defect has a likelihood to cause a minor functional failure in the cartridge, Non-Determinate (ND) result or complaints regarding to the appearance of the cartridge.

5 Responsibilities

Manufacturing and In-Process Testing are responsible for performing the activities described in this procedure as well as maintaining this procedure.

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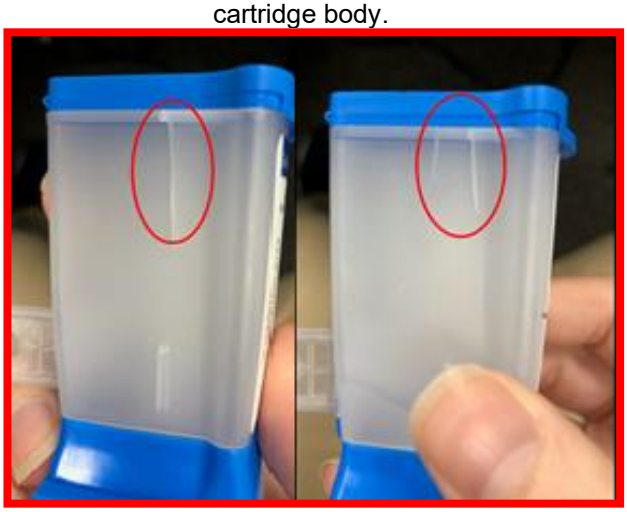
6 Procedure

6.1. Minor Visual Defects

6.1.1. Cracked Damage on body of the cartridge.

Table 1 – Cracked Damage on body of the cartridge	
Unacceptable/Minor Visual	**Acceptable**
Unacceptable Figure 1 – Cracked Damage on the cartridge body. 	Acceptable Figure 1 – No Evidence of Damage on body of cartridge. 

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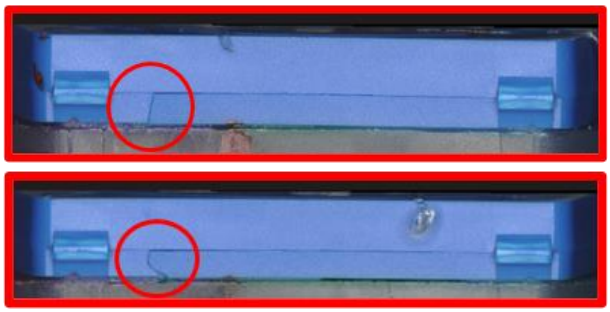
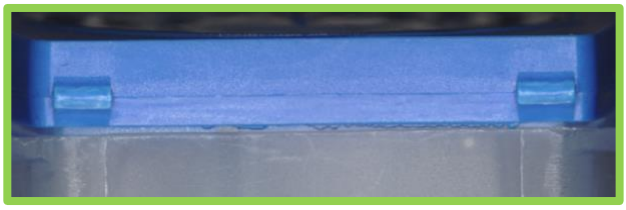
6.1.2. Damaged or cracked lid.

Table 2 – Damaged or cracked lid

Unacceptable/Minor Visual	Acceptable
Unacceptable Figure 2. Single crack at any part of the back lid, potential for lid to leak. 	Acceptable Figure 2 – No evidence of a single crack on the back of the lid. 
Unacceptable Figure 3a - Multi-cracked lid at the back of the lid, lid particulate is breaking off from lid and multi-crack on the side of the lid, potential for lid particulate to break off and cause leaks. All multi-cracked lids at the back or sides of the lid are unacceptable 	Acceptable Figure 3a - No evidence of multi-cracks on the lid. Single crack on the side of the lid. No signs of leakage 
Unacceptable Figure 4b - Multi-cracked lid at the front of the lid, lid particulate is breaking off from lid and potential for lid particulate to break off and cause leaks. 	Acceptable Figure 4b - No evidence of multi-cracks on the front of the lid. No signs of leakage  

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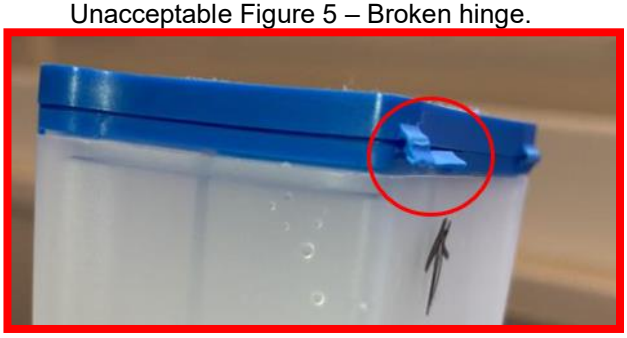
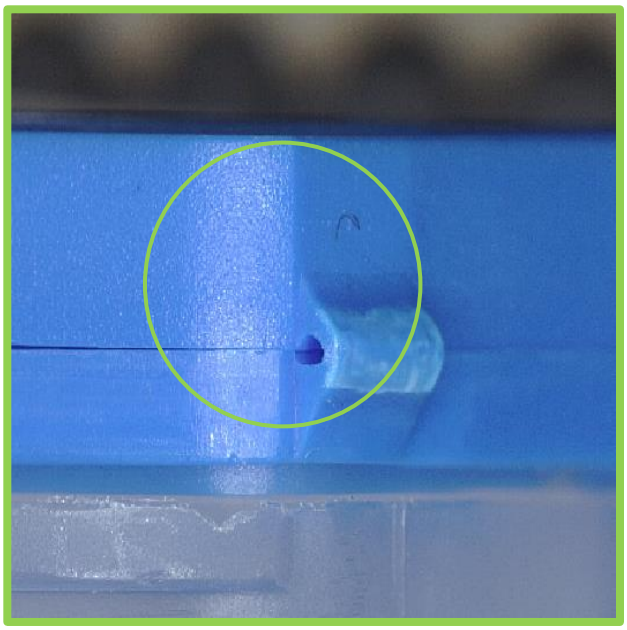
6.1.3. Broken Lid Hinge.

Table 3 – Broken Lid Hinge	
Unacceptable/Minor Visual	**Acceptable**
Unacceptable Figure 5 – Broken hinge. 	Acceptable Figure 5 – No broken hinge. 

6.1.4. Leakage from Cartridge.

Table 4 – Leakage from Cartridge	
Unacceptable/Minor Visual	**Acceptable**
Unacceptable Figure 6 – Evidence of leakage (foot leak, lid leak).  **(Information for IPT) In cases where cartridge(s) leaked onto the rest of the cartridges in the sample bag, locate, mark, and count the leaky cartridge(s) as a Minor Visual Failure(s) and replace the remaining cartridges in the time point.*	Acceptable Figure 6 – No evidence of leakage (no leak from the foot or lid). 

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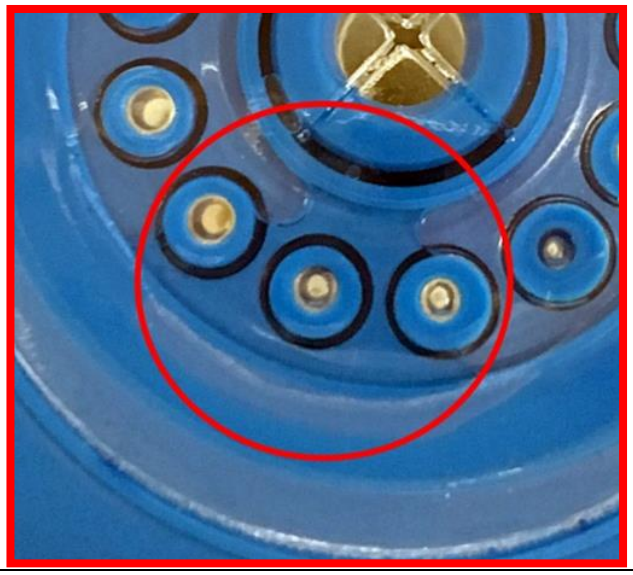
6.1.5. Liquid observed under the film seal.

Table 5 – Liquid observed under the film seal	
Unacceptable/Minor Visual	**Acceptable**
Unacceptable Figure 7 – Liquid observed under the film seal. 	Acceptable Figure 7 – No liquid observed under the film seal. 

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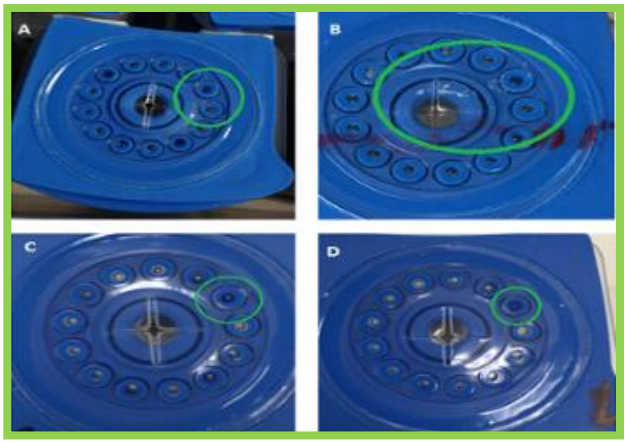
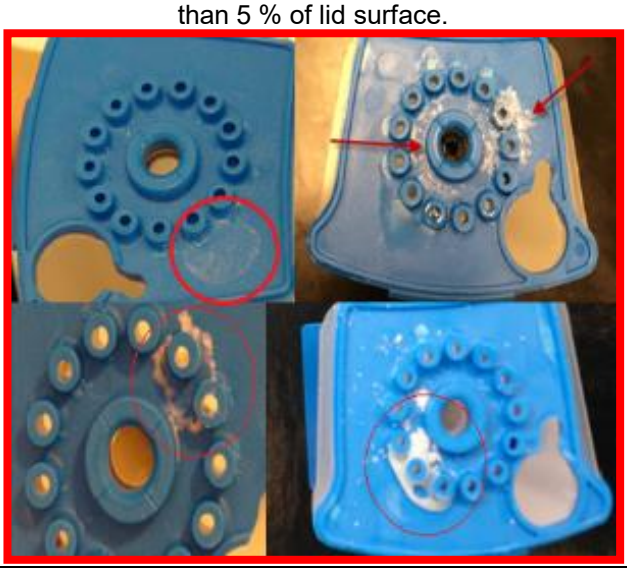
6.1.6. Crystallization on lid.

Table 6 – Crystallization on lid

Unacceptable/Minor Visual	Acceptable
Unacceptable Figure 8 – Moderate crystallization observed. 	Acceptable Figure 8 – Light crystallization observed through the film seal. 
Unacceptable Figure 9 - Any presence of liquid on lid surface, any presence of crystallization or liquid on or touching the plunger hole, moderate crystallization on more than 1 chimney or crystallization on more than 5 % of lid surface. 	Acceptable Figure 9 - Thin crystallization streaks on or under the lid, light crystallization on max 1 chimney or crystallization on max 5 % of lid surface. 

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6.1.7. Crystallization on outside of cart.

Table 7 – Crystallization on outside of cart	
Unacceptable/Minor Visual	**Acceptable**
Unacceptable Figure 10 – Moderate crystallization observed. 	Acceptable Figure 10 – No crystallization observed. 

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6.1.8.Lid Overwelding.

Table 8 – Lid Overwelding, e.g., plastic strings	
Unacceptable/Minor Visual	**Acceptable**
Unacceptable Figure 11 – Lid Overwelding with Plastic Hair. 	Acceptable Figure 11 – Stress whitening, small lid lip melting 
Unacceptable Figure 12 - Lid Overwelding, Plastic Strings, Damage to Upper and Front Lid 	Acceptable Figure 12 - Stress whitening, small lid lip melting. 

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6.1.9. Cracked/Broken chimneys.

Table 9 – Cracked/Broken chimneys.

Unacceptable/Minor Visual	Acceptable
Unacceptable Figure 13 – Cracked/Broken chimneys.  Unacceptable Figure 14 - Missing Chimney  Unacceptable Figure 15 - Chimney moved sideways / mashed chimney.  Unacceptable Figure 16 - Chimney moved under the lid 	Acceptable Figure 13 – Normal chimney appearance. 

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6.1.10. Film delamination.

Table 10 - Film delamination.

Unacceptable/Minor Visual	Acceptable
Unacceptable Figure 17 - Film delamination (flap) on any chimney or lid.  NOTE: Whether delamination is acceptable or not depends on the affected assay and the functional impact, see D12547 for more information	Acceptable Figure 14 - No delamination on any chimney or lid. 

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6.1.11. Poor Film Seal

NOTE: To differentiate lift/void from glare, view top-down then tilt 10–20°. Glare moves with angle; a true lift/void tends to remain.

NOTE: Poor outer seal (outer film seal) is referred to as POFS in PQC context.

Table 11A – Poor inner seal.

Unacceptable/Minor Visual	Acceptable
Unacceptable Figure 18 - Poor inner seal 	Acceptable Figure 15 –Good inner and outer seal 

Table 11B – Poor outer seal (Outer film seal / POFS).

Unacceptable/Minor Visual	Acceptable

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Unacceptable Figure 19 - Poor outer seal	Acceptable Figure 16 –Good inner and outer seal
	

6.1.12. Incomplete Chimney Melt/White Crescents around the ports

Table 12 – Incomplete Chimney Melt	
Unacceptable/Minor Visual	**Acceptable**

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Unacceptable/Minor Visual	Acceptable
Unacceptable Figure 19 – Incomplete Chimney Melt 	Acceptable Figure 15 – Complete Chimney melt 
 Unacceptable Figure 20 – White Crescents around the ports.	

6.1.13. Beads, Retain balls or debris in plunger hole.

Table 13 – Beads, Retain balls or debris in plunger hole	
Unacceptable/Minor Visual	**Acceptable**

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Unacceptable Figure 21 – Beads or debris in plunger hole. 	Acceptable Figure 16 – No beads or debris in plunger hole. 

6.1.14. Retain balls, beads, or debris in Chambers 2,3,5 and 8.

Table 14 – Retain balls, beads, or debris in Chambers 2,3,5 and 8.	
Unacceptable/Minor Visual	**Acceptable**
Unacceptable Figure 22 – Retain balls, beads, or debris in sample chamber (Chamber 3) or liquid reagent chambers (Chamber 2, 5, and 8). 	Acceptable Figure 17 – Reagent chambers and sample chambers (Chambers 2, 3, 5, and 8) are clear of beads and debris. 

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6.1.15. Damaged or loose Prefilter.

Table 15 – Damaged or loose Prefilter	
Unacceptable/Minor Visual	**Acceptable**
Unacceptable Figure 23 – Damaged Prefilter (e.g., out of place, cracked, loose). 	Acceptable Figure 18 – No Damage (e.g., Intact Pre-filter). 

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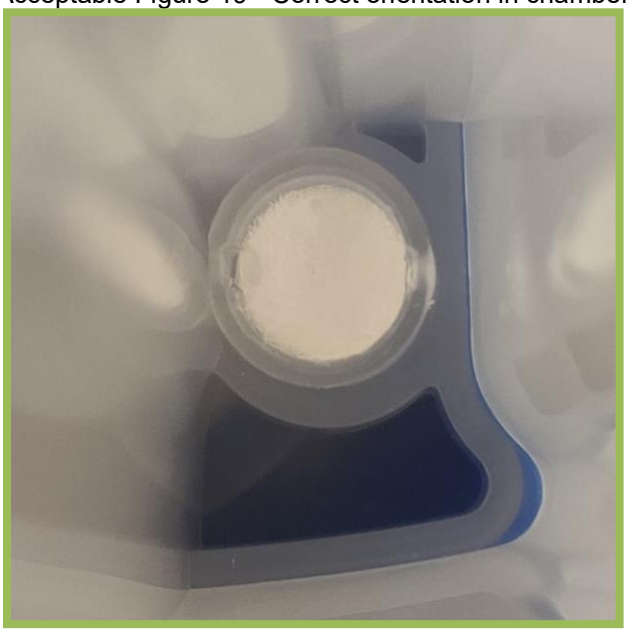
6.1.16. Upside-down prefilter

Table 16 - Upside-down prefilter

Unacceptable/Minor Visual	Acceptable
Unacceptable Figure 204 – Wrong orientation in chamber 	Acceptable Figure 19 - Correct orientation in chamber 
Unacceptable Figure 25 – Standalone filter in wrong orientation. 	Acceptable Figure 20 – Standalone filter in correct orientation. 

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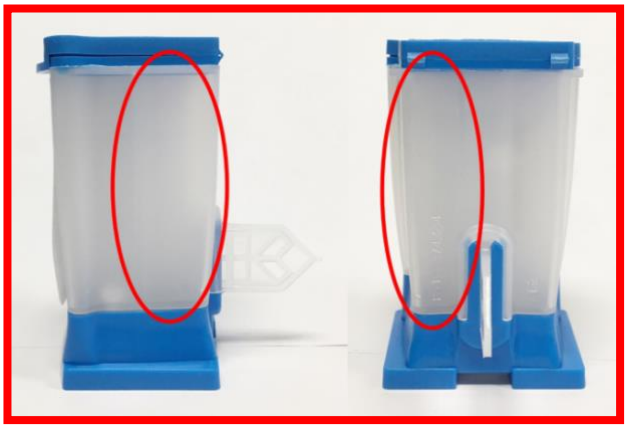
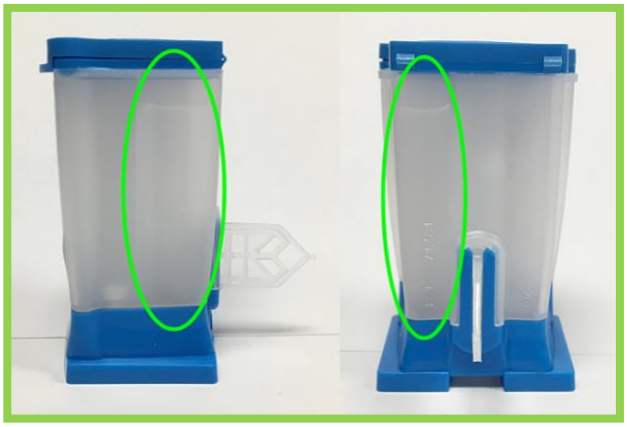
6.2. Major Visual Defects

6.2.1. Bent or Broken reaction tube

Table 17 - Bent or Broken reaction tube	
Unacceptable/Major Visual	**Acceptable**
Unacceptable Figure 26 - Damage (e.g., bent, broken reaction tube or broken reaction tube tip). 	Acceptable Figure 21 - No damage (e.g., reaction tube intact and reaction tube tip intact). 

6.2.2. Absence of reagents in assay/product specific Chambers

Table 18 - Absence of reagents in assay/product specific Chambers	
Unacceptable/Major Visual	**Acceptable**
Unacceptable Figure 27 - Absence of liquids on board reagents, if applicable (e.g., Chamber 2, 5 and 8). 	Acceptable Figure 22 - Presence of liquids on board reagents, if applicable (e.g., Chamber 2, 5 and 8). 

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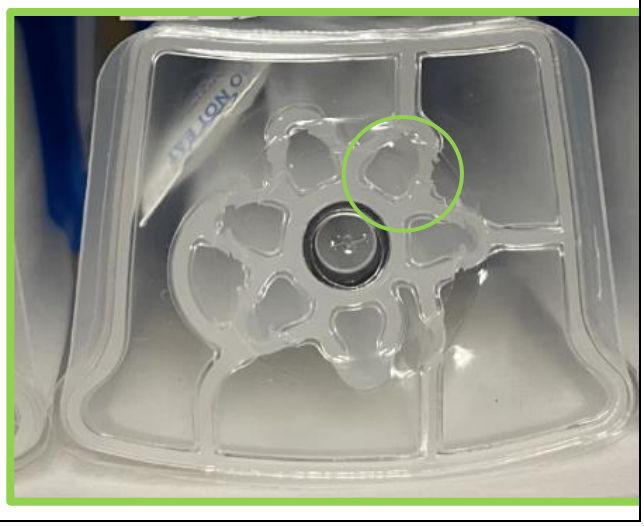
6.2.3. Missing or Loose Large Retain Ball

Table 19 – Missing or Loose Large Retain Ball (USPS Only)	
Unacceptable/Major Visual	**Acceptable**
Unacceptable Figure 28 – Loose Large Retain Ball visible at film seal	Acceptable Figure 23 – Large Retain Ball is properly inserted
	

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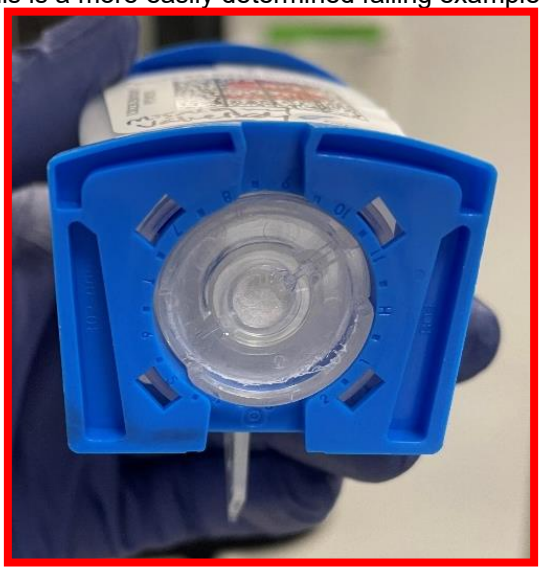
6.2.4.Misaligned Valve Body

Table 20 - Misaligned Valve Body (major visual)

Unacceptable/Major Visual	Acceptable
Unacceptable Figure 29 – Valve body is misaligned. (This is a more easily determined failing example). 	Acceptable Figure 24a - Valve body is correctly aligned. Arrow pointing at the H. 
Unacceptable Figure 29a – Arrow pointing outside the H. 	Acceptable Figure 24b – Valve body is correctly aligned. Arrow pointing, but borderline, at the H. 

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Unacceptable Figure 29b – Arrow pointing outside the H.

Acceptable Figure 24c – Valve body is correctly aligned. Arrow pointing, but borderline, at the H.

Acceptable Figure 24d – Valve body is correctly aligned. Arrow pointing, but borderline, at the H.

***Note**: The arrow needs to be pointing within the H. The arrow pointing at the line, or the line edge of the H is acceptable.

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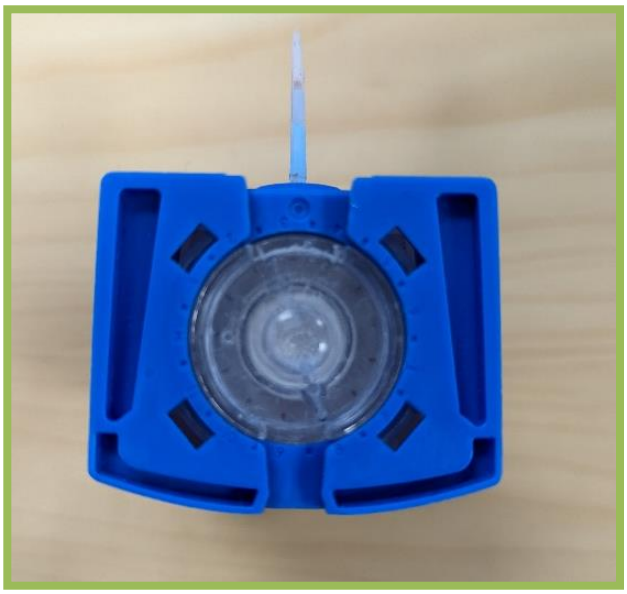
6.2.5. Chipped, Damaged or Deformed Valve Body

Table 21 - Chipped, Damaged or Deformed Valve Body	
Unacceptable/Major Visual	**Acceptable**
Unacceptable Figure 30 - Valve body is chipped/damaged/deformed. 	Acceptable Figure 25- Valve body shows no damage. 

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6.2.6. Missing or improper label placement

Table 22 - Missing or improper label placement (non-NFC cartridge)	
Unacceptable/Major Visual (non-NFC cartridge)	**Acceptable (non-NFC cartridge)**
Unacceptable Figure 31 – Unacceptable cartridge label placement (e.g., missing label, improper placement). 	Acceptable Figure 26 - Acceptable cartridge label (e.g., label present, proper placement). 

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Table 23 - Missing or improper label placement (NFC cartridge)	
Unacceptable/Major Visual (NFC cartridge)	**Acceptable (NFC cartridge)**
Unacceptable Figure 32 - Touching blue lid/foot and/or hanging off to the side.  Not a failure at IPT (see section 5.6.5.2 in D12547 for more information)	Acceptable Figure 27 - Label present and centered. 

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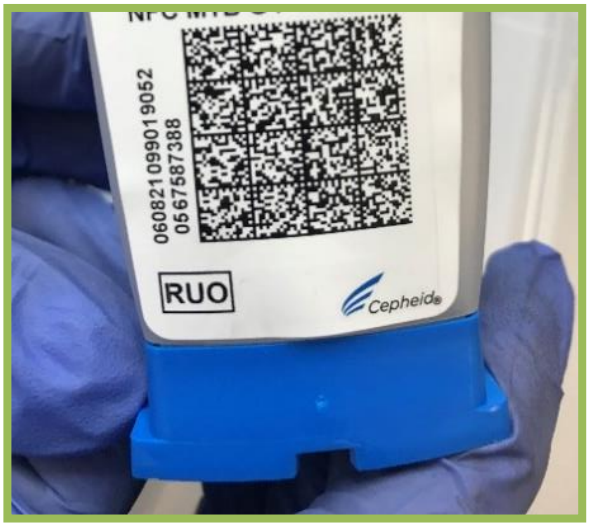
6.2.7.Label misprint, unreadable, faded or Unscannable Barcode

Table 24 - Label misprint, unreadable, faded or Unscannable Barcode	
Unacceptable/Major Visual	**Acceptable**
Unacceptable Figure 33 - Cartridge info incorrect, faded, or barcode cannot be scanned (e.g., illegible, unscannable). 	Acceptable Figure 28 - Barcode is scannable and cartridge information (e.g., Batch, Lot, Cartridge S/N) is clear, legible, and displays the right information. 

6.2.8.Punch in label

Table 25 - Punch in label (For NFC products ONLY)	
Unacceptable/Major Visual (NFC cartridge)	**Acceptable (NFC cartridge)**
Unacceptable Figure 34 - Punch in label.  Classified as a barcode failure at IPT (see section 5.6.5.2 in D12547 for more information)	Acceptable Figure 29 - No Punch. 

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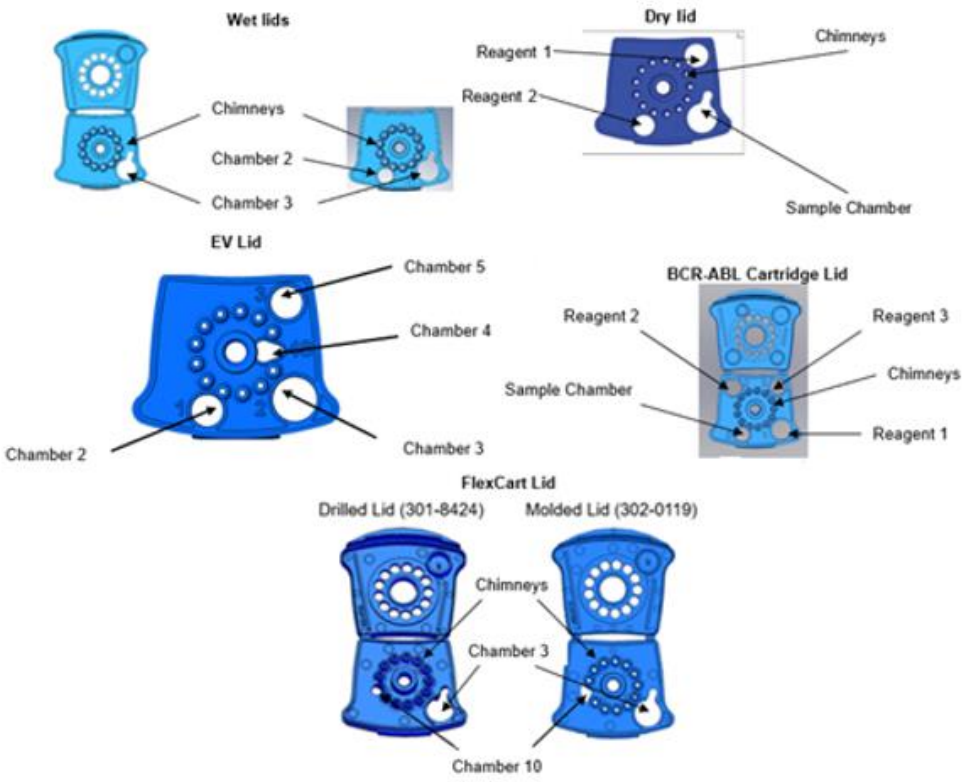
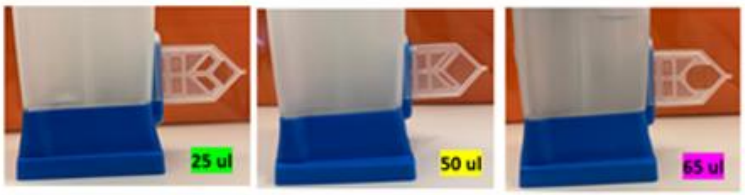
6.2.9. Incorrect components

Table 26 - Incorrect components (wrong lid, PCR-tube, or VBA-tube).
If a cartridge with incorrect components is discovered, it is unacceptable/major visual

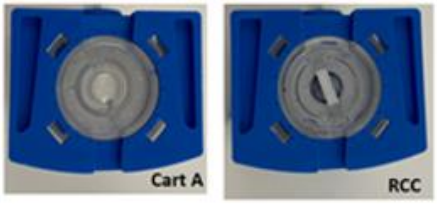
Lids



PCR-tubes



VBA-tubes



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6.2.10. Missing components

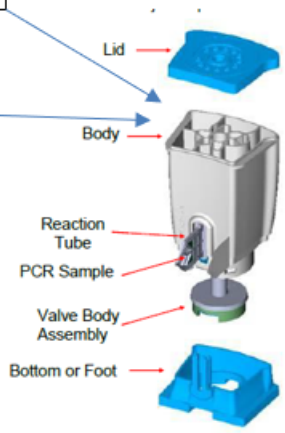
Table 27 - Missing components (missing plunger, missing pre-filter, missing funnel, etc.).

If a cartridge with missing components is discovered, it is unacceptable/major visual.

Some products feature a pre-filter at the bottom of the sample chamber or chamber 3(refer to Figure 15A).

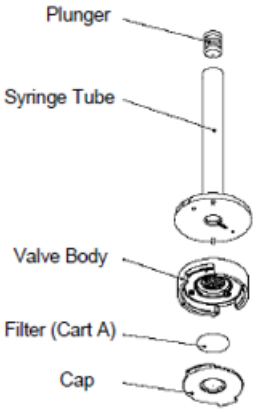
Illustration of a funnel (p/n# 300-8371)

For certain product assays such as SARS products a funnel is inserted into the sample chamber. (Chamber 3)



Component breakdown of GX cartridge.

The VBA assembly includes the plunger and a cartridge without a plunger will not run.



The VBA Assembly

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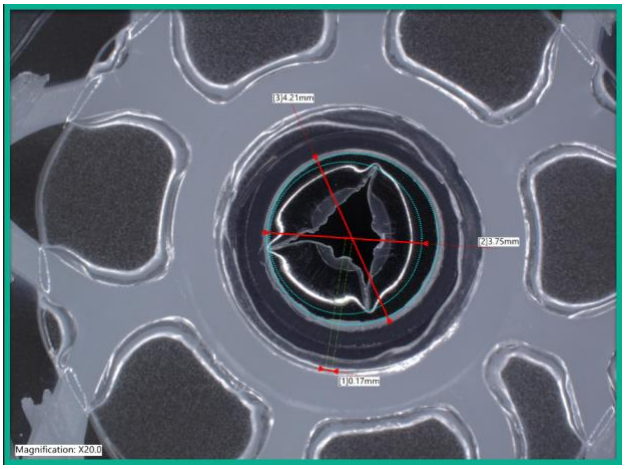
6.2.11 Missing Center Perforation

Table 28 – Missing Center Perforation on Top Film Seal (USPS Only)	
Unacceptable/Major Visual	**Acceptable**
Unacceptable Figure 35 – Missing Center perforation on top film seal 	Acceptable Figure 30 – Center perforation on top film seal Note: Image is magnifed for better image quality 

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6.3. Post-run cartridge inspection (QC testing only)

6.3.1. PCR tube film fuse artifact

6.3.1.1. Also sometimes referred to as PCR tube doughnut/donut.

6.3.1.2. This inspection applies ONLY to post-run inspection of QC functionally tested cartridges if potentially qualifying for a re-test per D12547 due to PCR tube film fuse artifact.

6.3.1.2.1. This inspection applies only to cartridges that underwent seal test AND functional testing and resulted in specific errors, see details in D12547.

6.3.1.2.2. If the post-run cartridge is not available for inspection or inspection result is inconclusive, the replicate may NOT be re-tested. A cartridge which may have been physically damaged post-run is considered not available for inspection.

6.3.1.2.3. PCR tube film fuse is not considered a visual failure but only used to motivate meeting criteria for re-test per D12547.

6.3.1.3. A cartridge is considered to have a PCR tube film fuse if meeting the following criteria:

6.3.1.3.1. The PCR tube is filled with liquid. The fused area must be surrounded by liquid.

6.3.1.3.2. The PCR tube film for a part of the PCR tube window is fused/stuck together with no liquid between the two film areas. This fused area must be at least 1mm in size (1 dimension) and may have different shapes (commonly diamond or oval shaped similar to the shape of the PCR tube window) and is usually located in the middle of the PCR tube. Refer to Table 29 for examples.

6.3.1.3.3. Consult with FI if guidance is needed.

6.3.1.4. The following observations do not qualify for PCR tube film fuse: Air bubble in PCR tube, precipitates in PCR liquid, wavy PCR tube film. Refer to Table 29 for examples.

6.3.1.4.1. Importantly, a PCR tube film fuse will not move while air bubbles or precipitates could move upon e.g., turning or gently tapping the cartridge, or gently touching of the PCR tube (which should be generally avoided and if, should be done under utmost care not to damage the PCR tube). Air bubbles may be observed additionally to PCR tube film fuses.

6.3.1.4.2. White/milky shadows may sometimes be observed on PCR films post-run. These are not considered PCR tube film fuses if no actual fuse is observed and there is still liquid between the two film pieces.

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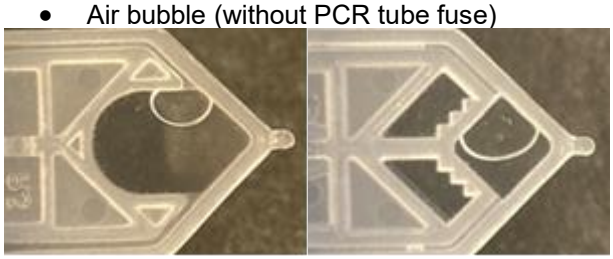
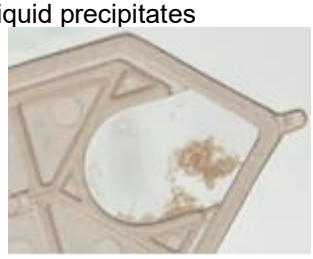
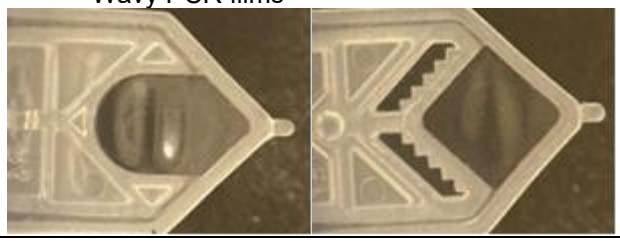
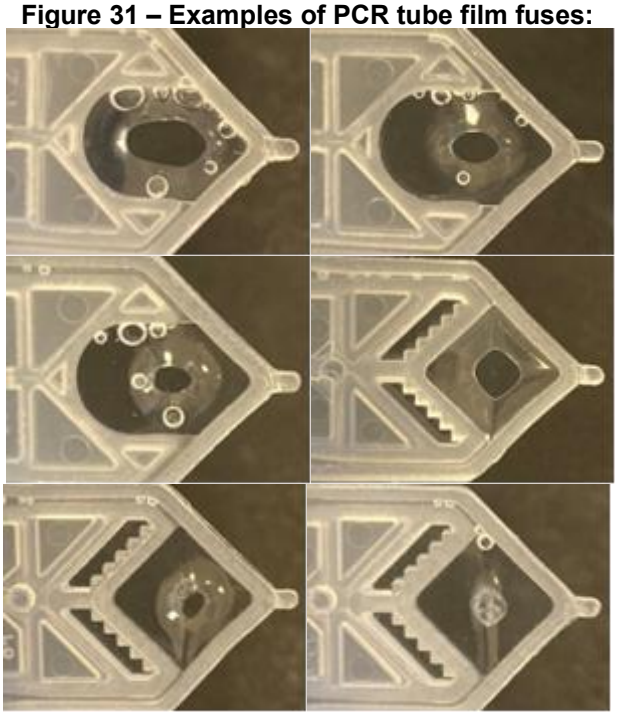
Table 29 – Post-run PCR tube film fuse inspection

NOT qualifying for PCR tube film fuse	Qualifying for PCR tube film fuse
Figure 36 – Visual findings that do NOT indicate a PCR tube film fuses: • PCR tube not liquid filled (observed best by comparing the light refraction of the tube to a non-run PCR tube empty cartridge and a post-run passing cartridge) • Air bubble (without PCR tube fuse)  • PCR liquid precipitates  • Wavy PCR films 	**Figure 31 – Examples of PCR tube film fuses:**  • Fused area must be at least 1mm in size (1 dimension) • PCR tube film fuse post-run may be combined with air bubbles (often multiple smaller ones)

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7 Document Revision History

Rev	Effective	Description of Changes
Y.1	Current	Correcting accidental text formatting in Rev. Y (red and underlined text in section 6.3)
Y	9/24/2024	Addition of Section 6.3. Post-run cartridge inspection (QC testing only): PCR tube film fuse artifact to help with implementation of re-test for PQC failures caused by PCR tube film fuse in D12547.
W	3/21/2024	Addition of Sec 6.1.12 with the Table 12 including Figure: 15,19, and 20 to help associates to easier identification of acceptable vs unacceptable incomplete chimney melt/white crescents around the ports.
V	03/08/2024	Added Table 27 – Missing Center Perforation on Top Film Seal *USPS Only
U	11/30/2023	Replaced Figure 28 with Figure 28a. Replaced Figure 23 with Figure 23a. Added Figures 28b, 23b, 23c and 23d to 6.2.4 to help associates to easier determine acceptable vs. unacceptable VBA misalignment.