

Form 2031 R3.0: Immune Deficiencies Pre-HSCT Data

Center: CRID:

Key Fields	
Sequence Number: _____	
Date Received: ____-____-____	
CIBMTR Center Number: _____	
CIBMTR Recipient ID: _____	
Has this patient's data been previously reported to USIDNET?	
<input type="checkbox"/> yes	<input type="checkbox"/> no
USIDNET ID: _____	
Today's Date: ____-____-____	
Date of HSCT for which this form is being completed: ____-____-____	
HSCT type: (check all that apply)	
<input type="checkbox"/>	Autologous
<input type="checkbox"/>	Allogeneic, unrelated
<input type="checkbox"/>	Allogeneic, related
<input type="checkbox"/>	Syngeneic (identical twin)
Product type: (check all that apply)	
<input type="checkbox"/>	Marrow
<input type="checkbox"/>	PBSC
<input type="checkbox"/>	Cord blood
<input type="checkbox"/>	Other product
specify _____	
<input type="checkbox"/>	If this is a report of a second or subsequent transplant, check here.
Continue with question 116.	

Disease Assessment at Diagnosis		Questions: 1 - 8
Disease assessment at diagnosis includes disease characteristics observed within six weeks of the date of diagnosis.		
1 What was the date of diagnosis of Immune Deficiency (ID)? ____-____-____		
2 What is the immune deficiency molecular abnormality? _____		
3 Specify molecular abnormality: _____		
4 Specify other abnormality: _____		
5 Is the mutated protein or enzyme expressed?		
<input type="checkbox"/>	yes	<input type="checkbox"/> no <input type="checkbox"/> Unknown
6 What is the pattern of inheritance for the genetic disorder?		
<input type="checkbox"/>	sporadic (no family history)	
<input type="checkbox"/>	x-linked, documented	
<input type="checkbox"/>	autosomal recessive, documented	
<input type="checkbox"/>	Unknown	
7 Are the parents of the patient consanguineous (related by blood ancestry)?		
<input type="checkbox"/>	yes	<input type="checkbox"/> no <input type="checkbox"/> Unknown
8 Are there other blood relatives in the patient's family with immunodeficiency disease?		
<input type="checkbox"/>	yes	<input type="checkbox"/> no <input type="checkbox"/> Unknown

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Laboratory Studies at Diagnosis		Questions: 9 - 50
Report findings prior to any first treatment of the primary disease for which the HSCT is being performed.		
9	Date CBC tested: (testing done within 6 weeks of diagnosis) ____ - ____ - ____	
10	WBC not tested	
	WBC: _____ x 10 <sup>9</sup> /L (x 10 <sup>3</sup> /mm <sup>3</sup> ) _____ x 10 <sup>6</sup> /L	
11	Lymphocytes not tested Lymphocytes: _____ %	
12	Eosinophils not tested Eosinophils: _____ %	
13	Polymorphonuclear leukocytes (PMN) not tested Polymorphonuclear leukocytes (PMN): _____ %	
14	Hemoglobin not tested	
	Hemoglobin: _____ g/dL _____ g/L _____ mmol/L	
	transfused RBC < 30 days from date of test	
15	Platelets not tested	
	Platelets: _____ x 10 <sup>9</sup> /L (x 10 <sup>3</sup> /mm <sup>3</sup> ) _____ x 10 <sup>6</sup> /L	
	transfused platelets < 7 days from date of test	
16	IgG not tested	
	IgG: _____ mg/dL _____ g/dL _____ g/L	
	17 Date tested: ____ - ____ - ____	
18	IgM not tested	
	IgM: _____ mg/dL _____ g/dL _____ g/L	
	19 Date tested: ____ - ____ - ____	
20	IgA not tested	
	IgA: _____ mg/dL _____ g/dL _____ g/L	
	21 Date tested: ____ - ____ - ____	
22	IgE not tested IgE: _____ IU/mL	
	23 Date tested: ____ - ____ - ____	
24	Did the recipient receive supplemental intravenous immunoglobulins (IVIG) prior to any first treatment of ID?	
	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> Unknown	
	25 Was therapy ongoing within one month of immunoglobulin testing?	
	<input type="checkbox"/> yes <input type="checkbox"/> no	
Lymphocyte Analysis		
Specify the following lymphocyte analyses performed prior to any disease treatment:		
26	Were lymphocyte analyses performed?	
	<input type="checkbox"/> yes <input type="checkbox"/> no	
	27 Date of most recent testing performed: ____ - ____ - ____	

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Center:



CRID:


28 Absolute lymphocyte count: \_\_\_\_\_ cells / uL (cells / (mm)\*\*3)

29  CD3 (T cells) not tested

CD3 (T cells) % of total lymphocytes \_\_\_\_\_ %

-- or --


CD3 (T cells) value \_\_\_\_\_  x 10<sup>9</sup>/L (x 10<sup>3</sup>/mm<sup>3</sup>)  
 x 10<sup>6</sup>/L

30  CD4 (T helper cells) not tested

CD4 (T helper cells) % of total lymphocytes \_\_\_\_\_ %



-- or --


CD4 (T helper cells) value \_\_\_\_\_  x 10<sup>9</sup>/L (x 10<sup>3</sup>/mm<sup>3</sup>)  
 x 10<sup>6</sup>/L

31  CD8 (cytotoxic T cells) not tested

CD8 (cytotoxic T cells) % of total lymphocytes \_\_\_\_\_ %

-- or --


CD8 (cytotoxic T cells) value \_\_\_\_\_  x 10<sup>9</sup>/L (x 10<sup>3</sup>/mm<sup>3</sup>)  
 x 10<sup>6</sup>/L

32  CD20 (B lymphocyte cells) not tested

CD20 (B lymphocyte cells) % of total lymphocytes \_\_\_\_\_ %



-- or --


CD20 (B lymphocyte cells) value \_\_\_\_\_  x 10<sup>9</sup>/L (x 10<sup>3</sup>/mm<sup>3</sup>)  
 x 10<sup>6</sup>/L

33  CD56 (natural killer (NK) cells) not tested

CD56 (natural killer (NK) cells) % of total lymphocytes \_\_\_\_\_ %



-- or --


CD56 (natural killer (NK) cells) value \_\_\_\_\_  x 10<sup>9</sup>/L (x 10<sup>3</sup>/mm<sup>3</sup>)  
 x 10<sup>6</sup>/L

34  CD4+/CD45RA+ (memory T cells) not tested

CD4+/CD45RA+ (naive T cells) % of total lymphocytes \_\_\_\_\_ %



-- or --

CD4+/CD45RA+ (naive T cells) value \_\_\_\_\_  x 10<sup>9</sup>/L (x 10<sup>3</sup>/mm<sup>3</sup>)  
 x 10<sup>6</sup>/L

35  CD4+/CD45RO+ (memory T cells) not tested

CD4+/CD45RO+ (memory T cells) % of total lymphocytes \_\_\_\_\_ %

-- or --

CD4+/CD45RO+ (memory T cells) value \_\_\_\_\_  x 10<sup>9</sup>/L (x 10<sup>3</sup>/mm<sup>3</sup>)  
 x 10<sup>6</sup>/L

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Antibody Response

36 Date antibody responses were assessed: (date closest to diagnosis, before any IVIG) \_\_\_\_ - \_\_\_\_ - \_\_\_\_

37 Bacteriophage phi X-174 or other neoantigen

☐ Absent ☐ Low ☐ Normal ☐ Not Tested

38 Diptheria

☐ Absent ☐ Low ☐ Normal ☐ Not Tested

39 Isohemagglutinin anti-A

☐ Absent ☐ Low ☐ Normal ☐ Not Tested

40 Isohemagglutinin anti-B

☐ Absent ☐ Low ☐ Normal ☐ Not Tested

41 Protein conjugated HIB or pneumococcal vaccine

☐ Absent ☐ Low ☐ Normal ☐ Not Tested

42 Tetanus

☐ Absent ☐ Low ☐ Normal ☐ Not Tested

43 Unconjugated pneumococcal polysaccharide: \_\_\_\_\_ / \_\_\_\_\_  
Number of serotypes producing a protective level / Total serotypes tested from vaccine

Lymphocyte Function

44 Date lymphocyte function was assessed: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

45 Anti-CD3

☐ Absent (<10% of control)  
☐ Low (10-30% of control)  
☐ Normal (>30% of control)  
☐ Not Tested

46 Candida antigen

☐ Absent (<10% of control)  
☐ Low (10-30% of control)  
☐ Normal (>30% of control)  
☐ Not Tested

47 Concavalin A (ConA)

☐ Absent (<10% of control)  
☐ Low (10-30% of control)  
☐ Normal (>30% of control)  
☐ Not Tested

48 Phytohemagglutinin (PHA)

☐ Absent (<10% of control)  
☐ Low (10-30% of control)  
☐ Normal (>30% of control)  
☐ Not Tested

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49 Pokeweed mitogen (PWM)

- ☐ Absent (<10% of control)
- ☐ Low (10-30% of control)
- ☐ Normal (>30% of control)
- ☐ Not Tested

50 Tetanus antigen

- ☐ Absent (<10% of control)
- ☐ Low (10-30% of control)
- ☐ Normal (>30% of control)
- ☐ Not Tested

Clinical Features Assessed between Diagnosis and the Start of the Preparative Regimen

Questions: 51 - 115

51 Site of infection: hepatitis

- ☐ yes
- ☐ no

Hepatitis Organism (1)

Questions: 52 - 53

52 Organism: \_\_\_\_\_

53 Specify: \_\_\_\_\_

54 If hepatitis was present, was it a prominent feature of ID?

- ☐ yes
- ☐ no

55 Site of infection: meningitis/encephalitis

- ☐ yes
- ☐ no

Meningitis / Encephalitis Organism (1)

Questions: 56 - 57

56 Organism: \_\_\_\_\_

57 Specify: \_\_\_\_\_

58 If meningitis / encephalitis was present, was it a prominent feature of ID?

- ☐ yes
- ☐ no

59 Site of infection: pneumonia

- ☐ yes
- ☐ no

Pneumonia Organism (1)

Questions: 60 - 61

60 Organism: \_\_\_\_\_

61 Specify: \_\_\_\_\_

62 If pneumonia was present. was it a prominent feature of ID?

- ☐ yes
- ☐ no

63 Site of infection: severe or protracted diarrhea

- ☐ yes
- ☐ no

Diarrhea Organism (1)

Questions: 64 - 65

64 Organism: \_\_\_\_\_

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65 Specify: \_\_\_\_\_

66 If diarrhea was present, was it a prominent feature of ID?

☐ yes ☐ no

67 Site of infection: systemic infection

☐ yes ☐ no

## Systemic Infection Organism (1)

Questions: 68 - 69

68 Organism: \_\_\_\_\_

69 Specify other organism : \_\_\_\_\_

70 If systemic infection was present, was it a prominent feature of ID?

☐ yes ☐ no

71 Site of infection: other infection

☐ yes ☐ no

## Other Infection Organism (1)

Questions: 72 - 74

72 Organism: \_\_\_\_\_

73 Specify: \_\_\_\_\_

74 Specify other infection site: \_\_\_\_\_

75 If other infection was present, was it a prominent feature of ID?

☐ yes ☐ no

## Clinical Status between Diagnosis and the Preparative Regimen

76 Did the recipient experience any of the following clinical features (between diagnosis and prior to the preparative regimen)?

☐ yes ☐ no

### Specify clinical features:

77 Is autoimmune hemolytic anemia present?

☐ yes ☐ no

78 Is autoimmune hemolytic anemia prominent?

☐ yes ☐ no

79 Are bone abnormalities present?

☐ yes ☐ no

80 Are bone abnormalities prominent?

☐ yes ☐ no

81 Is edema present?

☐ yes ☐ no

82 Is edema prominent?

☐ yes ☐ no

83 Is eosinophilia present?

☐ yes ☐ no

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**84** Is eosinophilia prominent?

☐ yes ☐ no

**85** Is failure to thrive (weight<5th percentile) present?

☐ yes ☐ no

**86** Is failure to thrive (weight < 5th percentile) prominent?

☐ yes ☐ no

**87** Is graft versus host disease due to blood transfusion present?

☐ yes ☐ no

**88** Is graft versus host disease due to blood transfusion prominent?

☐ yes ☐ no

**89** Is graft versus host disease due to maternal engraftment present?

☐ yes ☐ no

**90** Is graft versus host disease due to maternal engraftment prominent?

☐ yes ☐ no

**91** Is growth hormone deficiency present?

☐ yes ☐ no

**92** Is growth hormone deficiency prominent?

☐ yes ☐ no

**93** Is growth retardation (height<5th percentile) present?

☐ yes ☐ no

**94** Is growth retardation (height < 5th percentile) prominent?

☐ yes ☐ no

**95** Is hepatosplenomegaly present?

☐ yes ☐ no

**96** Is hepatosplenomegaly prominent?

☐ yes ☐ no

**97** Is hypoproteinemia present?

☐ yes ☐ no

**98** Is hypoproteinemia prominent?

☐ yes ☐ no

**99** Is lymphoproliferative disease present?

☐ yes ☐ no

**100** Is lymphoproliferative disease prominent?

☐ yes ☐ no

**101** Is maternal T-cell engraftment present?

☐ yes ☐ no

**102** Is maternal T-cell engraftment prominent?

☐ yes ☐ no

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**103** Is microcephaly present?

☐ yes ☐ no

**104** Is microcephaly prominent?

☐ yes ☐ no

**105** Is neutropenia present?

☐ yes ☐ no

**106** Is neutropenia prominent?

☐ yes ☐ no

**107** Is skin rash present?

☐ yes ☐ no

**108** Is skin rash prominent?

☐ yes ☐ no

**109** Is thrombocytopenia (< 100 x 10<sup>9</sup>/L) present?

☐ yes ☐ no

**110** Is thrombocytopenia (< 100 x 10<sup>9</sup>/L) prominent?

☐ yes ☐ no

**111** Are warts present?

☐ yes ☐ no

**112** Are warts prominent?

☐ yes ☐ no

**113** Are other clinical features present?

☐ yes ☐ no

**114** Are other clinical features prominent?

☐ yes ☐ no

**115** Specify other clinical features: \_\_\_\_\_

## Pre-HSCT Treatment for Immune Deficiency

Questions: 116 - 191

**116** Was treatment given (between diagnosis and prior to the preparative regimen)?

☐ yes ☐ no

**Prophylactic drugs paused for < 1 week should not be considered as "Prophylactic Drug Stopped."**

**117** Were antifungal drug(s) given as prophylaxis?

☐ yes ☐ no

**118** Were prophylactic antifungal drug(s) stopped?

☐ yes ☐ no

**119** ☐ Date prophylactic antifungal drug(s) stopped unknown

☐ date estimated

Date prophylactic antifungal drug(s) stopped: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**120** Were antiviral drug(s) given as prophylaxis?

☐ yes ☐ no



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**121** Were prophylactic antiviral drug(s) stopped?

☐ yes ☐ no

**122** ☐ Date prophylactic antiviral drug(s) stopped unknown

☐ date estimated

Date prophylactic antiviral drug(s) stopped: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**123** Was co-trimoxazole (Bactim, Septra) given as prophylaxis?

☐ yes ☐ no

**124** Was co-trimoxazole (Bactrim, Septra) stopped?

☐ yes ☐ no

**125** ☐ Date co-trimoxazole (Bactrim, Septra) stopped unknown

☐ date estimated

Date co-trimoxazole (Bactrim, Septra) stopped: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**Therapy paused for < 1 week should not be considered as "Therapy Stopped."**

**126** Was antithymocyte globulin (ATG, ATGAM, Thymoglobulin) given as therapy?

☐ yes ☐ no

**127** Was antithymocyte globulin (ATG, ATGAM, Thymoglobulin) stopped?

☐ yes ☐ no

**128** ☐ Date antithymocyte globulin (ATG, ATGAM, Thymoglobulin) stopped unknown

☐ date estimated

Date antithymocyte globulin (ATG, ATGAM, Thymoglobulin) stopped: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**129** Were systemic corticosteroids given as therapy?

☐ yes ☐ no

**130** Were systemic corticosteroids stopped?

☐ yes ☐ no

**131** ☐ Date therapeutic systemic corticosteroids stopped unknown

☐ date estimated

Date systemic corticosteroids stopped: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**132** Were topical corticosteroids given as therapy?

☐ yes ☐ no

**133** Were therapeutic topical corticosteroids stopped?

☐ yes ☐ no

**134** ☐ Date therapeutic topical corticosteroids stopped unknown

☐ date estimated

Date therapeutic topical corticosteroids stopped: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**135** Was cyclophosphamide (CTX, Cytoxan, Neosar) given as therapy?

☐ yes ☐ no

**136** Was therapeutic cyclophosphamide (CTX, Cytoxan, Neosar) stopped?

☐ yes ☐ no

**137** ☐ Date therapeutic cyclophosphamide (CTX, Cytoxan, Neosar) stopped unknown

☐ date estimated

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Date therapeutic cyclophosphamide (CTX, Cytosan, Neosar) stopped: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**138** Was cyclosporine (CsA, Neoral, Sandimmune) given as therapy?

☐ yes ☐ no

**139** Was therapeutic cyclosporine (CsA, Neoral, Sandimmune) stopped?

☐ yes ☐ no

**140** ☐ Date therapeutic cyclosporine (CsA, Neoral, Sandimmune) stopped unknown

☐ date estimated

Date therapeutic cyclosporine (CsA, Neoral, Sandimmune) stopped? \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**141** Was in vivo monoclonal antibody given as therapy?

☐ yes ☐ no

**Specify monoclonal antibody:**

**142** Was alemtuzumab (Campath) given as therapy?

☐ yes ☐ no

**143** Was therapeutic alemtuzumab (Campath) stopped?

☐ yes ☐ no

**144** ☐ Date therapeutic alemtuzumab (Campath) stopped unknown

☐ date estimated

Date therapeutic alemtuzumab (Campath) stopped: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**145** Was daclizumab (anti-CD25, Zenapax) given as therapy?

☐ yes ☐ no

**146** Was therapeutic daclizumab (anti-CD25, Zenapax) stopped?

☐ yes ☐ no

**147** ☐ Date therapeutic daclizumab (anti-CD25, Zenapax) stopped unknown

☐ date estimated

Date therapeutic daclizumab (anti-CD25, Zenapax) stopped: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**148** Was etanercept (Enbrel) given as therapy?

☐ yes ☐ no

**149** Was therapeutic etanercept (Enbrel) stopped?

☐ yes ☐ no

**150** ☐ Date therapeutic etanercept (Enbrel) stopped unknown

☐ date estimated

Date therapeutic etanercept (Enbrel) stopped: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**151** Was infliximab (anti-TNF- $\alpha$ , Remicade) given as therapy?

☐ yes ☐ no

**152** Was therapeutic infliximab (anti-TNF- $\alpha$ , Remicade) stopped?

☐ yes ☐ no

**153** ☐ Date therapeutic infliximab (anti-TNF- $\alpha$ , Remicade) stopped unknown

☐ date estimated

Date therapeutic infliximab (anti-TNF- $\alpha$ , Remicade) stopped: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

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**154** Was rituximab (anti-CD20, Rituxan, MabThera) given as therapy?

☐ yes ☐ no

**155** Was therapeutic rituximab (anti-CD20, Rituxan, MabThera) stopped?

☐ yes ☐ no

**156** ☐ Date therapeutic rituximab (anti-CD20, Rituxan, MabThera) stopped unknown

☐ date estimated

Date therapeutic rituximab (anti-CD20, Rituxan, MabThera) stopped: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**157** Was any other monoclonal antibody given as therapy?

☐ yes ☐ no

**158** Was therapeutic other monoclonal antibody stopped?

☐ yes ☐ no

**159** ☐ Date therapeutic other monoclonal antibody stopped unknown

☐ date estimated

Date therapeutic other monoclonal antibody stopped: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**160** Specify other monoclonal antibody: \_\_\_\_\_

**161** Was mycophenolate mofetil (MMF, Cellcept) given as therapy?

☐ yes ☐ no

**162** Was therapeutic mycophenolate mofetil (MMF, Cellcept) stopped?

☐ yes ☐ no

**163** ☐ Date therapeutic mycophenolate mofetil (MMF, Cellcept) stopped unknown

☐ date estimated

Date therapeutic mycophenolate mofetil (MMF, Cellcept) stopped: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**164** Was tacrolimus (FK506, Prograf) given as therapy?

☐ yes ☐ no

**165** Was therapeutic tacrolimus (FK506, Prograf) stopped?

☐ yes ☐ no

**166** ☐ Date therapeutic tacrolimus (FK506, Prograf) stopped unknown

☐ date estimated

Date therapeutic tacrolimus (FK506, Prograf) stopped: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**167** Was any other immunosuppressive drug given as therapy?

☐ yes ☐ no

**168** Was therapeutic other immunosuppressive drugs stopped?

☐ yes ☐ no

**169** ☐ Date other therapeutic immunosuppressive drug stopped unknown

☐ date estimated

Date therapeutic other other immunosuppressive drugs stopped: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**170** Specify other immunosuppressive drug: \_\_\_\_\_

**171** Was gene therapy performed (between diagnosis and prior to the preparative regimen)?

☐ yes ☐ no

**172** Specify date of infusion of gene therapy: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

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**173** Was the recipient considered to have failed gene therapy?

☐ yes ☐ no

**174** Did the recipient receive any other significant treatment(s) (between diagnosis and prior to the preparative regimen)?

☐ yes ☐ no

**175** Specify other treatment(s): \_\_\_\_\_

**176** Did the recipient receive parenteral nutrition (between diagnosis and prior to the preparative regimen)?

☐ yes ☐ no

**177** Did the recipient receive mechanical ventilation (between diagnosis and prior to the preparative regimen)?

☐ yes ☐ no

**178** Were any biologic specimens collected for this recipient (between diagnosis and prior to the preparative regimen)?

☐ yes ☐ no ☐ Unknown

**Specify if specimen(s) collected and available for future research:**

**179** DNA

☐ yes ☐ no

**180** Epstein-Barr virus (EBV)-transformed B-Cell line

☐ yes ☐ no

**181** Fibroblast cell line

☐ yes ☐ no

**182** Herpes virus saimiri-transformed T-cell line

☐ yes ☐ no

**183** Other T-cell line

☐ yes ☐ no

**184** Pathological specimen

☐ yes ☐ no

**185** Specify pathological specimen(s): \_\_\_\_\_

**186** Peripheral blood mononuclear cells (PBMC), frozen

☐ yes ☐ no

**187** RNA

☐ yes ☐ no

**188** Specify RNA source: \_\_\_\_\_

**189** Serum (pre-IVIG)

☐ yes ☐ no

**190** Other specimen

☐ yes ☐ no

**191** Specify other specimen(s): \_\_\_\_\_

First Name: \_\_\_\_\_ Last Name: \_\_\_\_\_

Phone number: \_\_\_\_\_ Fax number: \_\_\_\_\_

E-mail address: \_\_\_\_\_