Form 2150 R1.0: CMV / EBV / ADV / HHV-6 / BK Viral Infection Diagnostic and Treatment Form

Center: CRID:

Key Fields

Sequence Number: _____

Date Received: __ __ __ __ - __ __- __ __

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Event date: __ __ __ __ - __ __- __ __

Visit

○ Baseline ○ 100 day ○ 6 months ○ 1 year ○ 2 years ○ > 2 years

Specify: _____

Infection Episode

Questions: 1 - 31

1 Organism

- ○ 304 Adenovirus
- ○ 341 BK Virus
- ○ 303 Cytomegalovirus (CMV)
- ○ 318 Epstein-Barr Virus (EBV)
- ○ 317 Human herpesvirus 6 (HHV-6)

2 Date of diagnosis of infection: __ __ __ __ - __ __- __ __

Select all diagnostic tests used to determine the diagnosis of viral infection with a positive result. If test was performed, select every site from which the test was obtained and positive.

3 Polymerase chain reaction (PCR) assay

○ Yes ○ No

4 Specify sample source (that supported the diagnosis of infection) (check all that apply)

- ☐ Blood (includes whole blood, bone marrow, serum, or plasma)
- ☐ Bronchial fluid (BAL)
- ☐ Cerebrospinal fluid (CSF)
- ☐ Pericardial fluid
- ☐ Stool
- ☐ Tissue
- ☐ Urine
- ☐ Other

5 Specify other sample source: _____

6 Date sample collected: __ __ __ __ - __ __- __ __

Detection in blood / serum by PCR

7 Highest viral copies reported: (since date of diagnosis) _____ ○ copies/mL ○ copies/L ○ IU/mL ○ IU/L

8 Date highest viral load detected: __ __ __ __ - __ __- __ __

PCR Tissue Sample(s) (1)

Questions: 9 - 11

Specify tissue for PCR assay:

9 Specify tissue

- ○ Central nervous system (CNS) (includes brain)
- ○ GI tract (esophagus, stomach, intestines)
- ○ Heart / myocardium
- ○ Liver
- ○ Lung
- ○ Lymph node
- ○ Skin
- ○ Spleen
- ○ Other

10 Specify other tissue: _____

11 Date sample collected: __ __ __ __ - __ __- __ __

12 Culture

○ Yes ○ No

13 Specify sample source (that supported the diagnosis of infection) (check all that apply)

- ☐ Blood (includes whole blood, bone marrow, serum, or plasma)
- ☐ Bronchial fluid (BAL)
- ☐ Cerebrospinal fluid (CSF)
- ☐ Pericardial fluid
- ☐ Stool
- ☐ Tissue
- ☐ Urine
- ☐ Other

14 Specify other sample source: _____

Specify tissue:

15 Specify tissue (check all that apply)

- ☐ Central nervous system (CNS) (includes brain)
- ☐ GI tract (esophagus, stomach, intestines)
- ☐ Heart / myocardium
- ☐ Liver
- ☐ Lung
- ☐ Lymph node
- ☐ Skin
- ☐ Spleen
- ☐ Other

16 Specify other tissue: _____

17 Were there histopathology findings of viral cytopathic changes? (on biopsy)

○ Yes ○ No

18 Specify biopsy site (that supported the diagnosis of infection) (check all that apply)

- ☐ Central nervous system (CNS) (includes brain)
- ☐ GI tract (esophagus, stomach, intestines)
- ☐ Heart / myocardium
- ☐ Liver
- ☐ Lung
- ☐ Lymph node
- ☐ Skin
- ☐ Spleen
- ☐ Other

19 Specify other site: _____

20 Were immunohistochemistry (IHC) stains obtained on tissue biopsy? (that supported the diagnosis of infection)

○ Yes ○ No

21 Specify biopsy site (that supported the diagnosis of infection) (check all that apply)

- ☐ Central nervous system (CNS) (includes brain)
- ☐ GI tract (esophagus, stomach, intestines)
- ☐ Heart / myocardium
- ☐ Liver
- ☐ Lung
- ☐ Lymph node
- ☐ Skin
- ☐ Spleen
- ☐ Other

22 Specify other site: _____

23 Radiographic findings of infection (e.g. X-ray, CT, PET, or MRI)

○ Yes ○ No

24 Specify imaging site (that supported the diagnosis of infection) (check all that apply)

- ☐ Central nervous system (CNS) (includes brain)
- ☐ GI tract (esophagus, stomach, intestines)
- ☐ Heart / myocardium
- ☐ Liver
- ☐ Lung
- ☐ Lymph node
- ☐ Skin
- ☐ Spleen
- ☐ Other

25 Specify other site: _____

Select all clinical signs present on the date (± 1 day) of diagnosis of infection

26 Requiring oxygen
○ Yes ○ No

27 Hepatomegaly
○ yes ○ no

28 Splenomegaly
○ yes ○ no

29 Diarrhea
○ Yes ○ No

30 Neurologic symptoms (e.g. confusion, irritability, seizures, drowsiness)
○ Yes ○ No

31 Enlarged lymph nodes / lymphadenopathy
○ Yes ○ No

Hematologic Findings at Diagnosis of Infection

Questions: 32 - 50

Provide values closest to the date of diagnosis of the infection (± 7 days)

32 WBC
○ Known ○ Unknown

33 _____ ○ x 10^9/L (x 10^3/mm^3) ○ x 10^6/L

34 Neutrophils
○ Known ○ Unknown

35 _____ %

36 Monocytes
○ Known ○ Unknown

37 _____ %

38 Lymphocytes
○ Known ○ Unknown

39 _____ %

40 Platelets
○ Known ○ Unknown

41 _____ ○ x 10^9/L (x 10^3/mm^3) ○ x 10^6/L

42 Serum creatinine
○ Known ○ Unknown

43 _____ ○ mg/dL ○ mmol/L ○ µmol/L

44 Upper limit of normal for your institution: _____ ○ mg/dL ○ mmol/L ○ µmol/L

45 ALT (SGPT)
○ Known ○ Unknown

46 _____ ○ U/L ○ µkat/L

47 Upper limit of normal for your institution: _____ ○ U/L ○ µkat/L

48 IgG
○ Known ○ Unknown

49 _____ ○ mg/dL ○ g/dL ○ g/L

50 Date sample collected: __ __ __ __ - __ __ - __ __

Therapy

Questions: 51 - 76

Specify all therapy received by the recipient from *7 days prior* to the date of infection diagnosis until the end of the reporting period for this form. If the recipient received the medication, please record the date that the medication started.

51 Did the recipient receive any therapy between 7 days prior to the date of infection diagnosis and the date of contact for this reporting period?

○ Yes ○ No

52 Antiviral drugs

○ Yes ○ No

Antiviral drugs (1)

Questions: 53 - 57

53 Specify antiviral drug

○ Acyclovir (Zovirax) ○ Brincidofovir (CMX-001) ○ Cidofovir (Vistide) ○ Foscarnet (Foscavir) ○ Ganciclovir (Cytovene) ○ Letermovir (Prevymis)

○ Maribavir ○ Valacyclovir (Valtrex) ○ Valganciclovir (Valcyte) ○ Other antiviral drug

54 Specify other antiviral drug: _____

55 Was therapy started more than 7 days prior to the date of infection diagnosis?

○ Yes ○ No

56 Date started: __ __ __ __ - __ __- __ __ ☐ Date estimated

57 Was this therapy still being given at 30 days (± 3 days) after the date of diagnosis of infection?

○ Yes ○ No

58 Was combination chemotherapy used to treat EBV-associated malignancies? (e.g. CHOP, etc.)

○ Yes ○ No

59 Was therapy started more than 7 days prior to the date of infection diagnosis?

○ Yes ○ No

60 Date started: __ __ __ __ - __ __- __ __ ☐ Date estimated

61 Was this therapy still being given at 30 days (± 3 days) after the date of diagnosis of infection?

○ Yes ○ No

62 Rituximab (Rituxan)

○ yes ○ no

63 Was therapy started more than 7 days prior to the date of infection diagnosis?

○ Yes ○ No

64 Date started: __ __ __ __ - __ __- __ __ ☐ Date estimated

65 Was this therapy still being given at 30 days (± 3 days) after the date of diagnosis of infection?

○ Yes ○ No

66 IVIG (polyclonal IV immune globulin)

○ yes ○ no

67 Was therapy started more than 7 days prior to the date of infection diagnosis?

○ Yes ○ No

68 Date started: __ __ __ __ - __ __- __ __ ☐ Date estimated

69 Was this therapy still being given at 30 days (± 3 days) after the date of diagnosis of infection?

○ Yes ○ No

70 Cytogam (CMV hyperimmune gamma globulin)

○ Yes ○ No

71 Was therapy started more than 7 days prior to the date of infection diagnosis?

○ Yes ○ No

72 Date started: __ __ __ __ - __ __- __ __ ☐ Date estimated

73 Was this therapy still being given at 30 days (± 3 days) after the date of diagnosis of infection?

○ Yes ○ No

74 Cellular therapy (e.g., virus specific T-cells, DLI)

○ yes **- Also complete Pre-CTED Form 4000**

○ no

75 Other drug used to treat this infection

○ yes ○ no

76 Specify: _____

Infection Status at the Time of Evaluation for this Reporting Period

Questions: 77 - 77

Center: CRID:

77 What was the infection status at the time of evaluation for this reporting period?

○ Ongoing ○ Improved ○ Resolved ○ Unknown

First Name: _____

Last Name: _____

E-mail address: _____

Date: __ __ __ __ - __ __ - __ __