Laboratory Criteria for confirmation of the Disease - L form (2019)

1.	**Measles**	A presumptive case with • Detection of anti-measles IgM antibody by enzyme immunoassay (EIA) **OR** • Measles virus detection through PCR from throat swab or urine or nasopharyngeal swab **OR** • Direct epidemiologic linkages to a case confirmed by one of the above methods **SOURCE: Immunisation Division shared on 28.05.2019**
2.	**Diphtheria**	A presumptive case with • Isolation of Corynebacterium diphtheriae **OR** • Detection by PCR from a clinical specimen. **SOURCE: Immunisation Division shared on 28.05.2019**
3.	**Pertussis**	A presumptive case with • Isolation of B. pertussis from a clinical specimen **OR** • Single serum positive for IgG antibody **OR** • PCR positive for pertussis **SOURCE: Immunisation Division shared on 28.05.2019**
4.	**Polio**	An AFP case is ‘confirmed’ as polio only by the • isolation of wild poliovirus from any stool specimen in WHO accredited laboratory **SOURCE: Immunisation Division shared on 28.05.2019**

5.	**Rubella**	Rubella infection is confirmed by any one of the following laboratory tests • Positive serologic test for rubella IgM antibody **OR** • Detection of rubella-virus specific nucleic acid by polymerase chain reaction; **OR** • Isolation of rubella virus **SOURCE: Immunisation Division shared on 28.05.2019**
6.	**Human Rabies**	A presumptive case or death is confirmed by • Detection by FAT on skin biopsy (ante mortem) **OR** • Detection of rabies viral antigens by direct fluorescent antibody test (FAT) or by ELISA in clinical specimens, preferably brain tissue (collected post mortem) **OR** • FAT positive after inoculation of brain tissue, saliva or CSF in cell culture, or after intracerebral inoculation in mice or in suckling mice **OR** • Detectable rabies-neutralizing antibody titre in the serum or the CSF of an unvaccinated person **OR** • Detection of viral nucleic acids by PCR on tissue collected post mortem or intra vitam in a clinical specimen (brain tissue or skin, cornea, urine or saliva). **SOURCE: National Rabies Control Programme shared on 12.06.2019**

7.	**Leptospirosis**	A presumptive case with • IgM ELISA positive **OR** • Isolation of leptospires from clinical specimen **OR** • Four fold or greater rise in the MAT titer between acute and convalescent phase serum specimens run in parallel **OR** • PCR test. **SOURCE: Programme for prevention and control of Leptospirosis shared on 12.06.2019**
8.	**Hepatitis-A**	A presumptive case with • IgM antibodies to hepatitis A(anti HAV IgM) in serum/plasma ***Note:*** *The sample has to be tested as per testing algorithm for jaundiced patient according to guidelines of National Viral Hepatitis Control Programme* **SOURCE: National Viral Hepatitis Control Programme shared on 10.06.2019**
9.	**Hepatitis-E**	A presumptive case with • IgM antibody to hepatitis E virus (anti HEV IgM) in serum/plasma ***Note:*** *The sample has to be tested as per testing algorithm for jaundiced patient according to guidelines of National Viral Hepatitis Control Programme* **SOURCE: National Viral Hepatitis Control Programme shared on 10.06.2019**

10.	**Dengue/DHF**	A presumptive case with • Demonstration of dengue virus antigen in serum sample by NS1-ELISA. **OR** • Demonstration of IgM antibody titre by ELISA in single serum sample. **OR** • IgG seroconversion in paired sera after 2 weeks with four fold increase of IgG titres. **OR** • Detection of viral nucleic acid by polymerase chain reaction (PCR). **OR** • Isolation of the virus (Virus culture positive) from serum, plasma or leucocytes. **SOURCE: NVBDCP shared on 11.06.2019**
11.	**Chikungunya**	A presumptive case with • MAC ELISA- Presence of virus specific IgM antibodies in a single serum sample collected in acute or convalescent stage. Four-fold increase in IgG values in samples collected at least three weeks apart. **OR** • Virus isolation **OR** • Presence of viral RNA by RT-PCR **SOURCE: NVBDCP shared on 11.06.2019**

12.	**Japanese Encephalitis**	A Presumptive case with • Presence of IgM antibody in serum and/or CSF **OR** • Four fold difference in IgG antibody titre in paired sera **OR** • Virus isolation from brain tissue **OR** • Antigen detection by immunofluoroscence Nuclic acid detection by PCR **SOURCE: Guidelines for surveillance of Acute Encephalitis Syndrome shared on 25.06.2019**
13.	**Malaria**	A suspected case with • Positive malaria parasite in peripheral blood smear detected through microscopy **OR** • Positive antigen based detecting Rapid Diagnostic Test (RDTs) **OR** • Positive molecular diagnostic test. Note: On rare occasions, the presence of occult malaria infection in a blood or organ donor, confirmed retrospectively, by the demonstration of malaria parasites in the recipient of the blood or organ. **Source: NVBDCP shared on 09.07.2019**
14.	**Kala Azar**	A 'suspect' Kala azar patient found positive on screening with rapid diagnostic test. **OR** In cases with past history of Kala-azar or in those with high suspicion of kala azar with negative RDT test result but found positive by bone marrow/spleen aspirate for LD bodies. **Source: NVBDCP shared on 09.07.2019**

15.	**Cholera**	An presumptive Acute Diarrheal case with • Culture **OR** • Polymerase chain reaction (PCR) test **SOURCE: WHO–recommended standards for surveillance of selected Vaccine-preventable diseases, 2018 (modified on 28.05.2019)**
16.	**Shigellosis**	An acute diarrhoea/dysentery case with • isolation of Shilgella species from stool sample **SOURCE: Public Health Laboratory Network case definitions, May 2000 (modified on 28.05.2019)**
17.	**Typhoid**	A presumptive case with • Confirmed positive culture (blood, bone marrow, stool, urine) **OR** • Molecular methods of S. typhi/ S paratyphi. **SOURCE: WHO–recommended standards for surveillance of selected Vaccine-preventable diseases,2018 (modified on 28.05.2019, NCDC)**

18.	**Mumps**	A presumptive case with • Isolation of mumps virus by culture or reverse transcription-polymerase chain reaction (RT-PCR) from an appropriate clinical specimen (buccal/oral swab, throat swab, urine, and cerebrospinal fluid) **OR** • Seroconversion from IgG negative to IgG positive as determined by any standard serological assay in the absence of mumps immunization in the preceding six weeks **OR** • In unvaccinated individuals, significant (≥ fourfold) rise in serum mumps IgG titre as determined by any standard serological assay **SOURCE: WHO–recommended standards for surveillance of selected Vaccine-preventable diseases,2018 (modified on 28.05.2019, NCDC)**
19.	**Chicken pox**	A presumptive case with • Detection of VZV DNA (using PCR) **OR** • direct antigen detection of VZV from an appropriate clinical specimen e.g. direct fluorescent antibody (DFA) **OR** • isolation using viral culture* **OR** • seroconversion* or a significant rise (fourfold or greater) in varicella-zoster IgG titer between acute and convalescent sera by any validated serologic assay **SOURCE: WHO–recommended standards for surveillance of selected Vaccine-preventable diseases, 2018 (modified on 28.05.2019, NCDC)**

20.	**Influenza**	A presumptive case of ILI or SARI with • Conventional PCR or real-time reverse transcription PCR (RT-PCR) **OR** • Any validated nucleic acid based test. **SOURCE: NCDC, Technical Guidelines on H1N1 (revised on 25.02.2019)**
21.	**Meningococcal Meningitis**	A presumptive case with • Grams staining and/Or Antigen detection by Latex Agglutination Test in CSF **OR** • Isolation of N. meningitidis from blood or CSF **OR** • Detection of N. meningitidis-specific nucleic acid in a specimen obtained from a normally sterile body site (e.g., blood or CSF), using a validated polymerase chain reaction (PCR) assay **SOURCE: NCDC, CD alert Nov 2009 (modified on 28.05.2019, NCDC)**
22.	**Yellow Fever**	A presumptive case, in the absence of recent yellow fever vaccination, • Yellow-fever- specific IgM is found in the serum, **OR** • A fourfold or greater rise in IgG levels is found in PAIRED acute and convalescent sera, **OR** • Yellow fever virus is isolated in cell culture or laboratory animals, or in case of positive post-mortem liver histopathology, **OR** • Yellow fever antigens are detected in tissues by immunohistochemistry **OR** • Yellow fever virus genomic sequences are detected in blood or organs by molecular diagnostic techniques such as Reverse Transcription Polymerase Chain Reaction (RT- PCR) **SOURCE: NCDC updated guidelines on Yellow fever**

23.	**Nipah Virus Disease**	A presumptive case with • Nipah virus RNA identified by PCR from respiratory secretions, urine, or cerebrospinal fluid **OR** • Isolation of Nipah virus from respiratory secretions, urine or cerebrospinal fluid **SOURCE: NCDC updated guidelines on Nipah Virus Disease**
24.	**Ebola Virus Disease**	A presumptive case with • Positive IgM antibody **OR** • Positive PCR **OR** • Viral isolation. **SOURCE: NCDC updated guidelines on Ebola Virus Disease**
25.	**Zika Virus Disease**	A presumptive case with • laboratory positive result for the specific detection of ZIKV by RT-PCR **SOURCE: NCDC, CD alert March 2016 (modified on 28.05.2019, NCDC)**
26.	**Scrub Typhus**	A presumptive case with • IgM ELISA is positive for scrub typhus. **OR** • O. Tsutsugamushi DNA is detected in eschar samples or whole blood by PCR **OR** • Seroconversion or four fold rise or fall in antibody titres in paired sera detected by ELISA or Indirect Immune Fluorescence Assay (IFA) or Indirect Immunoperoxidase Assay (IPA). **SOURCE: Updated by Zoonosis Division NCDC on 2.07.2019**

27.	**Kyasanur Forest Disease**	A presumptive case with • Detection of KFDV-specific viral RNA by reverse transcription polymerase chain reaction (RT-PCR) or real time RT-PCR from blood or tissues **OR** • Positive for immunoglobulin M (IgM) enzyme-linked immunosorbent assay (ELISA) for KFD **OR** • Isolation of KFDV in cell culture or in a mouse model, from blood or tissues **SOURCE: Updated by Zoonosis Division NCDC on 2.07.2019**
28.	**Crimean Congo Hemorrhagic Fever (CCHF)**	A presumptive case with • Detection of CCHF virus genome by validated RT - PCR in a clinical specimen AND/ OR sequencing **OR** • Detection by ELISA or IFA of specific IgM antibodies against CCHF virus **OR** A 4-fold increase in specific IgM antibodies against CCHF virus in two specimens collected in the acute and convalescence phases **OR** • CCHF virus isolation **SOURCE: Updated by Zoonosis Division NCDC on 2.07.2019**
29.	**Brucellosis**	A presumptive case with • A titre of 1:160 or more by Standard Agglutination Test (SAT). o An attempt to demonstrate 4 fold rise in antibody titre should be made. o Prozone phenomenon (antibody excess) should be kept in mind. **OR** • Positive by IgM / IgG ELISA **OR** • Detection of Brucella DNA in clinical sample by PCR. **OR** • Isolation of Brucella in clinical sample. **SOURCE: Updated by Zoonosis Division NCDC on 2.07.2019**

30.	**Anthrax**	A presumptive case with • Isolation and identification of B. anthracis from relevant samples **and** identified by colony morphology, microscopy and biochemical test. • Gamma phage lysis **OR** validated PCR (Toxin and capsule genes) may be used for final confirmation (Validated PCR on direct clinical sample is also acceptable). **SOURCE: Updated by Zoonosis Division NCDC on 2.07.2019**
31.	**West Nile Fever**	An AES case with • Viral detection by reverse transcription polymerase chain reaction (RT-PCR) assay, **OR** • IgM antibody capture enzyme-linked immunosorbent assay (ELISA); PRNT is recommended to rule out cross reactions and confirmation. **OR** • Virus isolation by cell culture. **SOURCE: Updated by Zoonosis Division NCDC on 2.07.2019**

32.	**Plague**	A presumptive case with
		• An isolate from a clinical sample identified as Y.pestis, and two of the four following tests must be positive:
		  • Y.pestis biochemical profile.
		  • Bacteriophage lysis of culture.
		  • F1 Antigen detection
		  • PCR (pla gene, F1 gene)
		OR
		• A fourfold difference in anti F1 antibody titre in paired serum samples
		OR
		• Direct validated PCR on clinical specimen.
		
		SOURCE: Updated by Zoonosis Division NCDC on 2.07.2019

33.	**MERS Co-V**	A presumptive case with • The presence of viral nucleic acid can be confirmed by either positive results for nucleic acid amplification assays, such as o reverse transcription polymerase chain reaction (RT-PCR), for at least two specific genomic targets **OR** o A single positive target with sequencing of a second target. **OR** • Demonstration of sero-conversion in 2 samples ideally taken at least 14 days apart, by a screening (ELISA, IFA) and a neutralization assay. **SOURCE: Updated by Zoonosis Division NCDC on 2.07.2019**