L form Case Definitions 2024

Sl. No.	Disease Condition	Case Definition
1.	**Influenza**	A presumptive case of ILI or SARI with • Conventional Polymerase Chain Reaction (PCR) or real-time reverse transcription PCR (RT-PCR) **OR** • Any validated nucleic acid-based test (Annexure 1) ***Source:*** *NCDC, Technical Guidelines on H1N1, 2019*
2.	**Cholera**	A presumptive case of acute diarrheal disease with • Culture (and identification of Vibrio cholera) **OR** • Polymerase Chain Reaction (PCR) test ***Source:*** *WHO–recommended standards for Surveillance of selected Vaccine-Preventable Diseases, 2018*
3.	**Shigellosis**	An acute diarrhea / dysentery case with • Isolation of Shigella species from stool sample (Culture) **OR** • Nucleic acid-based tests ***Source:*** *Public Health Laboratory Network case definitions, May 2000*
4.	**Typhoid**	A presumptive case with • Positive culture (from any clinical specimen) **OR** • Molecular methods of S. typhi/ S. paratyphi ***Source:*** *WHO–recommended standards for Surveillance of selected Vaccine-Preventable Diseases, 2018*

5.	**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*
6.	**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*
7.	**Meningitis (Meningococcal disease)**	A presumptive case with • Antigen detection by Latex Agglutination Test in CSF **OR** • Isolation of N. meningitides from blood or CSF **OR** • Detection of N. meningitides-specific nucleic acid in a specimen (e.g., blood or CSF), using a validated polymerase chain reaction (PCR) assay ***Source:*** *NCDC, CD Alert November,2009*

8.	**Diphtheria**	A presumptive case with • Isolation of *Corynebacterium diphtheriae* from a clinical specimen by culture **OR** • Detection by PCR from a clinical specimen ***Note:*** *Throat swab/pieces of membrane collection within 4 weeks of onset of sore throat.* ***Source:*** *Immunization Division shared on 13.10.2023*
9.	**Pertussis**	A presumptive case with • Isolation of Bordetella pertussis from a clinical specimen by culture **OR** • Detection by PCR from a clinical specimen **OR** • Single serum positive for IgG antibody *Note: Nasopharyngeal swab collection within 4 weeks of onset of cough and serology sample collection within 12 weeks ofonset of cough.* ***Source:*** *Immunization Division shared on 13.10.2023*

10.	**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** • Isolation of measles virus **OR** • Direct epidemiologic linkages to a case confirmed by one of the above methods *Note: Virology sample collection within 7 days and serology sample collection within 28 days of onset of rash.* ***Source:*** *Immunization Division shared on 13.10.2023*

11.	**Rubella**	A presumptive case with • Detection of anti-rubella IgM antibody by enzyme immunoassay (EIA) **OR** • Rubella virus detection through PCR from throat swab or urine or nasopharyngeal swab **OR** • Isolation of rubella virus **OR** • Direct epidemiologic linkages to a case confirmed by one of the above methods *Note: Virology sample collection within 7 days and serology sample collection within 28 days of onset of rash.* ***Source:*** *Immunization Division shared on 13.10.2023*
12.	**Polio**	An AFP case is 'confirmed' as polio only by the • Isolation of wild poliovirus from any stool specimen in the WHO accredited laboratory *Note: Stool sample collection within 14 days of paralysis onset, and no later than 60 days following paralysis onset.* ***Source:*** *Immunization Division shared on 13.10.2023*

13.	**Mumps**	A presumptive case • Positive by 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 **OR** • Isolation of mumps virus by culture from an appropriate clinical specimen (buccal/oral swab, throat swab, urine, and cerebrospinal fluid) ***Source:*** *WHO–recommended standards for Surveillance of selected Vaccine-Preventable Diseases,2018 (Modified on 28.05.2019, NCDC)*

14.	**Chicken pox**	A presumptive case with • Detection of VZV DNA by Polymerase Chain Reaction (PCR) **OR** • Direct antigen detection of VZV from an appropriate clinical specimen {e.g. direct fluorescent antibody (DFA) testing} **OR** • Virus isolation **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)
15.	**Malaria**	A confirmed malaria case (or infection) is one in which the parasite has been detected by a diagnostic test, i.e. microscopy,rapid diagnostic test, or molecular diagnostic test. ***Source:*** *NCVBDC shared on 22.09.2023*

16.	**Dengue**	A case compatible with the clinical description (see below) of Dengue Fever with at least one of the following: • Isolation of dengue virus (Virus culture+VE) from serum, plasma, leucocytes • Demonstration of IgM antibody titre by ELISA positive in single serum sample • Demonstration of dengue virus antigen in serum sample by NS1-ELISA • IgG seroconversion in paired sera after 2 weeks of fourfold increase of IgG titre • Detection of viral nucleic acid by polymerase chain reaction (PCR) Clinical Description of Dengue: The clinical description of Dengue Fever includes an acute febrile illness of 2-7 daysduration with two or more of the following manifestations: • Headache • Retro-orbital pain • Myalgia • Arthralgia • Rash • Haemorrhagic Manifestations ***Source:*** *NCVBDC shared on 22.09.2023*
17.	**Chikungunya**	A patient meeting both the clinical and laboratory criteria: **Clinical criteria:** Acute onset of fever and severe arthralgia/arthritis with or without skin rash and residing or having leftan epidemic area 15 days prior to onset of symptoms **Laboratory criteria:** At least one of the following tests done in the acute phase of illness **Direct evidence:** Virus isolation / Presence of viral RNA by RT-PCR **Indirect evidence:** • Presence of virus specific IgM antibodies in single serum sample collected in acute or convalescent stage. • Four-fold increase in IgG values in samples collected at least three weeks apart. *Source: NCVBDC shared on 22.09.2023*

18.	**Japanese Encephalitis**	Every AES is a Suspect case of JE and it has to be laboratory confirmed **with any one** of the following markers: • Presence of IgM antibody in serum and/ or CSF to JE Virus • Fourfold difference in IgM antibody titre in paired sera • Virus isolation from brain tissue • Antigen detection by immunofluroscence Nucleic acid detection by PCR *Source: NCVBDC shared on 22.09.2023*
19.	**West Nile Virus**	An Acute Encephalitic Syndrome (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 02.07.2019*
20.	**Kala-azar**	A presumptive case is confirmed by: • Rapid diagnostic test (RDT) **OR** • Polymerase Chain Reaction (PCR) **OR** • Biopsy *[#]In cases with past history of kala-azar or with high suspicion and with negative RDT results, confirmation can be done by examination of bone marrow/spleen aspirate for Leishmania donovani (LD) bodies at an appropriate level equipped with such skills and facilities.* ***Source:*** *NCVBDC shared on 26.09.2023*

21.	**Human Rabies**	A suspected or probable case that is laboratory-confirmed* *Laboratory confirmation is done by one or more of the following: • Detection of viral antigens in clinical samples (e.g., brain tissue, nuchal skin biopsy, saliva) • Detection of viral nucleic acids in clinical samples (e.g., brain tissue, CSF, nuchal skin biopsy, saliva, urine) • Detection of virus-specific antibodies in the cerebrospinal fluid (CSF) • Detection of virus-specific antibodies in the serum of an unvaccinated person • Demonstration of a four-fold or higher rise in virus-specific antibody titres in paired sera of previously vaccinated individuals • Isolation of rabies virus from a clinical sample (e.g. brain tissue, saliva) in cell culture or laboratory animal ***Source:*** *Centre for One Health shared on 15.12.2023*
22.	**Plague**	A presumptive case with an isolate from a clinical sample identified as *Y. pestis* and two of the four following tests must bepositive • Y. pestis biochemical profile • Bacteriophage lysis of culture • F1 Antigen detection • PCR (pla gene, F1 gene) **OR** • A fourfold difference in anti F1 antibody titer in paired serum samples **OR** • Direct validated PCR on clinical specimen

23.	**Leptospirosis**	A case compatible with the clinical description of leptospirosis with at least one of the following: 1. High titre of IgM antibodies in ELISA (evaluated with locally determined cut off) for single clinical sample*. 2. Four-fold or greater rise or persistent titre (in case of antibiotic given) in the MAT (total antibodies) between acuteand convalescent-phase serum specimens run parallel. 3. Seroconversion on ELISA in paired serology (demonstrating conversion of IgM to IgG antibodies). **A single serum sample showing high titres of IgM antibodies may indicate acute infectionThese 1-3 tests are the preferred tests as ELISA are widely acceptable* Other: Isolation and Validated PCR can be done in patients who have not received antibiotic and in early stage ofdiseases (preferably less than 7 days) ***Source:*** *CAZD shared on 10.10.2023*
24.	**Scrub Typhus**	A case compatible with the clinical description of scrub typhus with at least one of the following: 1. High titre of IgM antibodies in ELISA (evaluated with locally determined cut off) for single clinical sample*. 2. A four-fold rise in the Weil-Felix test (total antibodies) between acute and convalescent-phase serum specimens runin parallel. 3. Seroconversion on ELISA/ IFAT (demonstrating the conversion of IgM to IgG antibodies). **A single serum sample showing high titres of IgM antibodies may indicate acute infection.These 1-3 tests are the preferred tests as ELISA are widely acceptable* Other: Isolation and Validated PCR can be done in patients who have not received antibiotic and in early stage of diseases(preferably less than 7 days) ***Source:*** *CAZD shared on 10.10.2023*

25.	**Brucellosis**	A case compatible with the clinical description of brucellosis with at least one of the following: 1. High titre of IgM antibodies in ELISA (evaluated with locally determined cutoff) for single clinical sample*. 2. A four-fold rise in the SAT (total antibodies) between acute and convalescent-phase serum specimens run parallel. 3. Seroconversion on ELISA in paired serology (demonstrating the conversion of IgM to IgG antibodies). **A single serum sample showing high titres of IgM antibodies may indicate acute infectionThese 1-3 tests are the preferred tests as ELISA are widely acceptable* Other: Isolation and Validated PCR can be done in patients who have not received antibiotic and in early stage ofdiseases (preferably less than 7 days) ***Source:*** *CAZD shared on 10.10.2023*
26.	**Anthrax**	A presumptive case with: • Isolation and identification of *B. anthracis* from relevant samples and identified by colony morphology, microscopyand biochemical tests • Gamma phage lysis OR Validated PCR (Toxin and capsule genes) may be used for final confirmation (ValidatedPCR on direct clinical sample is also acceptable)
27.	**CCHF (Crimean Congo Hemorrhagic Fever)**	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 andconvalescence phases **OR** • CCHF virus isolation

28.	**KFD (Kyasanur Forest Disease)**	A presumptive case with: • Detection of KFDV-specific viral RNA by reverse transcription polymerase chain reaction (RT-PCR) or real timeRT-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
29.	**Nipah Virus Disease**	A presumptive case with: • Nipah virus RNA identified by Polymerase Chain Reaction (PCR) from respiratory secretions, urine, or cerebrospinal fluid. **OR** • Isolation of Nipah virus from respiratory secretions, urine, or cerebrospinal fluid ***Source:*** *NCDC, CD Alert September, 2023*
30.	**Zika Virus Disease**	A presumptive case with positive result for the specific detection of ZIKV by Reverse Transcription Polymerase Chain Reaction (RT-PCR) ***Source:*** *NCDC, CD Alert March, 2016*
31.	**Monkeypox**	A presumptive case is confirmed for monkeypox virus by • Polymerase Chain Reaction (PCR) **OR** • Sequencing ***Source:*** *NCDC, CD Alert July, 2022*

32.	**Ebola**	A presumptive case with: • IgM antibody positive by enzyme-linked immunosorbent assay (ELISA) **OR** • Polymerase Chain Reaction (PCR) **OR** • Virus isolation ***Source:*** *NCDC, CD Alert December, 2022*
33.	**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)

34.	**MERS CoV**	A presumptive case with: • The presence of viral nucleic acid can be confirmed by either positive results for nucleic acid amplification assays such as: ❖ reverse transcription polymerase chain reaction (RT-PCR), for at least two specific genomic targets **OR** ❖ 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 test (ELISA) and confirmation by a microneutralization assay
35.	**Marburg Virus Disease**	A presumptive case with: • IgM antibody positive by enzyme-linked immunosorbent assay (ELISA) **OR** • Virus isolation ***Source:*** *NCDC, CD Alert July, 2023*

Annexure 1

Validated Human Influenza Testing Kits (Updated on 11.04.2024*)

Kits evaluated at NIV and passed ICMR criteria				
Sr No	**Manufacturer**	**Kit name**	**Virus detected**	**Remark**
1	Siemens HealthCare Pvt Ltd	IMDX Flu Panel (InfA/InfB/H1N1/H3N2)	Influenza A and its subtype H1N1, H3N2	
2	ALTONA DIAGNOSTICS Pvt Ltd	FlexStar® SARS-CoV-2 Type & FLU RT-PCR	SARS-CoV-2, Influenza	Kit does not differentiate between Influenza A and Influenza B.
3	Invitrogen Bioservices India Pvt. Ltd	TaqPath Covid-19, FluA, FluB Combo Kit	SARS-CoV-2, Influenza A, Influenza B	
4	M/s Kriya Medical Technologies Pvt. Ltd	KRIVIDA TRIVUS RESPI PANEL	SARS-CoV-2, Influenza A or Influenza B, RSV A or B	Kit does not differentiate between Influenza A and Influenza B, similarly RSV A & RSV B
5	HiMedia Laboratories Pvt. Ltd	Hi-PCR Influenza Multiplex Probe PCR Kit	Influenza A and its subtype H1N1, Influenza B	Kit does not detect H3N2 subtype
6	HiMedia Laboratories Pvt. Ltd	Hi-PCR COVID FLU RSV Multiplex Probe PCR Kit	Influenza A and its subtype H1N1, H3N2, Influenza B, SARS-CoV-2, RSV	Kit does not differentiate between RSV A & RSV B
7	Mylab Discovery Solutions Pvt. Ltd	Patho Detect Human Influenza Detection Kit	Influenza A and its subtype H1N1, H3N2, Influenza B	
8	**NIV Single tube assay for detection of SARS Cov 2**	**Technology been transferred to Mylab discovery solutions**		
9	**NIV Kits (Multiplex single tube assay for Influenza A,B and SARS CoV 2**	**Technology transfer is in process with three companies Huwel Life sciences Meril Diagnostics Mylab solutions**		
***Note: The list of validated Human Influenza testing kits will be updated from time to time**				

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