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COMMISSION DECISION

of 19 March 2002

laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council

(notified under document number C(2002) 1043)

(2002/253/EC)

(OJ L 86, 3.4.2002, p. 44)

Amended by:

	Official Journal		
	No	page	date
►**M1** Commission Decision 2003/534/EC of 17 July 2003	L 184	35	23.7.2003

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community ([1]), and in particular Article 3(c) thereof,

Whereas:

(1) Member States should communicate information on the epidemiological development and emergence of public health threats due to communicable diseases using the Community network in a way which allows comparisons to be made for preventive and control action to be taken at Community and national level.

(2) For comparability of such information, the setting up of common case definitions is a prerequisite even where disease-specific surveillance networks have not yet been put in place. As soon as this Decision comes into effect these case definitions should be used for reporting to the Community network, and should comply with regulations on individual data protection.

(3) The case definitions which allow comparable reporting should comprise a tiered system allowing Member States' structures and/or authorities flexibility in communicating information on diseases and special health issues. In particular, these case definitions will facilitate reporting on diseases listed in Commission Decision 2000/96/EC ([2]).

(4) Case definitions should be constructed to enable all Member States to participate in the reporting to the greatest extent possible, using data from their existing systems. They should allow for different levels of sensitivity and specificity according to the different goals of information collection and they should be easy to amend.

(5) The measures provided for in this Decision are in accordance with the opinion of the Committee set up by Decision No 2119/98/EC,

HAS ADOPTED THIS DECISION:

Article 1

For the purposes of submitting data for the epidemiological surveillance and control of communicable diseases under the provisions of Decision No 2119/98/EC, and in particular Article 4 thereof, Member States shall apply the case definitions specified in the Annex.

Article 2

This Decision will be adapted to the extent necessary on the basis of the latest scientific data.

([1]) OJ L 268, 3.10.1998, p. 1.
([2]) OJ L 28, 3.2.2000, p. 50.

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Article 3

This Decision shall apply as of 1 January 2003.

Article 4

This Decision is addressed to the Member States.

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ANNEX

CASE DEFINITIONS FOR COMMUNICABLE DISEASES LISTED IN DECISION 2000/96/EC

GENERAL PRINCIPLES FOR THE APPLICATION OF THESE CASE DEFINITIONS

— Unless specifically stated, only symptomatic cases are to be reported, however, asymptomatic infections are to be regarded as cases, if the infection has therapeutic or public health implications.

— A 'case with an epidemiological link' is a case that has either been exposed to a confirmed case, or has had the same exposure as a confirmed case (e.g. eaten the same food, stayed in the same hotel, etc.).

— A three-tiered system with following levels is to be used:

  — confirmed case: verified by laboratory analysis,

  — probable case: clear clinical picture, or linked epidemiologically to a confirmed case,

  — possible case: indicative clinical picture without being a confirmed or probable case.

  The classification on these different levels might vary according to the epidemiology of the individual diseases.

— Clinical symptoms listed are only given as indicative examples and not exhaustive.

— For most diseases, several 'criteria for laboratory diagnosis' are listed. Unless otherwise stated, only one of these is needed to confirm a case.

— N.A. in the case definition list means 'not applicable'.

INTRODUCTORY NOTES

1. The information reported in this document is intended only for uniform reporting/comparability of data within the Community network. The clinical description gives a general outline of the disease and does not necessarily indicate all the features needed for clinical diagnosis of the disease.

2. The laboratory criteria for diagnosis reported here may be fulfilled with different testing methods. However, when specific techniques are indicated, their use is recommended.

CASE DEFINITIONS

ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) AND HIV INFECTION

1. ***Aids***

Clinical description

Includes all human immunodeficiency virus (HIV)-infected individuals who have any of the 28 clinical conditions listed in the European AIDS surveillance case definition.

Criteria for diagnosis

I. *Adults and adolescents*: 1993 European AIDS surveillance case definition (see Annex II).

II. *Children aged <13 years*: 1995 revision of the European case definition for AIDS surveillance in children (see Annex III).

Case classification

Possible:	N.A.
Probable:	N.A.
Confirmed:	A case meeting the European AIDS case definition.

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2. ***HIV infection***

Clinical description

The diagnosis is based on laboratory criteria of HIV infection or a diagnosis of AIDS.

Laboratory criteria for diagnosis

I. *Adults, adolescents and children aged ≥ 18 months*

- — Positive result on a screening HIV antibody test confirmed by a different HIV antibody test
- — Detection of HIV nucleic acid (RNA or DNA)
- — Detection of HIV by HIV p24 antigen test, including neutralisation assay
- — HIV isolation (viral culture)

II. *Children <18 months*

- — Positive results on two separate determinations (excluding cord blood) from one or more of the following HIV detection tests:
  - — HIV nucleic acid (RNA or DNA) detection
  - — HIV p24 antigen test, including neutralisation assay, in a child ≥ 1 month of age
  - — HIV isolation (viral culture).

Case classification

Possible:	N.A.
Probable:	N.A.
Confirmed:	A case that is laboratory confirmed or meets the European AIDS case definition.

ANTHRAX

Clinical description

Inhalational anthrax

After inhalation of *Bacillus anthracis* and a brief prodrome acute febrile respiratory failure develops with hypoxia, dyspnoa and radiological evidence of mediastinal widening.

Cutaneous anthrax

A skin lesion evolving from a papule, through a vesicular stage to a depressed black eschar with surrounding oedema. The lesion is usually painless but there may be constitutional disturbance (fever and malaise).

Gastointestinal anthrax

Following consumption of raw contaminated food a syndrome of severe abdominal pain, diarrhoea, fever and septicaemia.

Laboratory criteria for diagnosis

- — Isolation and confirmation of *B. anthracis* from specimens collected from a normally sterile site (e.g. blood or CSF) or lesion of other affected tissue (skin, lung or gut);
- — both of the following:
  - — evidence of *B. anthracis* DNA (e.g. by PCR) from specimens collected from a normally sterile site (e.g. blood or CSF) or lesion of other affected tissue (skin, lung or gut),
  - — demonstration of *B. anthracis* in a clinical specimen by immunohistochemical staining of affected tissue (skin, lung or gut).

Nasal swab without indication of disease does not contribute to diagnosis of a case.

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Case classification

Possible:	N.A.
Probable:	A probable case is defined as: — a clinically compatible case of illness without isolation of *B. anthracis* and no alternative diagnosis, but with laboratory evidence of *B. anthracis* by one supportive laboratory test, — a clinically compatible case of anthrax epidemiologically linked to a confirmed environmental exposure, but without corroborative laboratory evidence of *B. anthracis* infection.
Confirmed:	A clinically compatible case that is laboratory confirmed.

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BOTULISM

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Clinical description

Clinical picture compatible with botulism, e.g. symptoms such as diplopia, blurred vision and bulbar weakness. Symmetric paralysis may progress rapidly.

Laboratory criteria for diagnosis

— Detection of botulinum toxin in serum, stool, stomach content or patient's food

— Isolation of *Clostridium botulinum* from stool.

Case classification

Possible:	N.A.
Probable:	A clinically compatible case with an epidemiological link
Confirmed:	A clinically compatible case that is laboratory confirmed.

BRUCELLOSIS

Clinical description

Clinical picture compatible with brucellosis, e.g. acute or insidious onset of fever, night sweats, undue fatigue, anorexia, weight loss, headache and arthralgia.

Laboratory criteria for diagnosis

— Demonstration of a specific antibody response

— Demonstration by immunofluorescence of *Brucella sp*. in a clinical specimen

— Isolation of *Brucella sp*. from a clinical specimen

For probable case:

— A single high titre.

Case classification

Possible:	N.A.
Probable:	A clinically compatible case with an epidemiological link, or a case with an isolated high titre
Confirmed:	A clinically compatible case that is laboratory confirmed.

CAMPYLOBACTER INFECTION

Clinical description

Clinical picture compatible with campylobacteriosis, e.g. diarrhoeal illness of variable severity.

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Laboratory criteria for diagnosis

— Isolation of *Campylobacter sp*. from any clinical specimen.

Case classification

Possible:	N.A.
Probable:	A clinically compatible case with an epidemiological link
Confirmed:	A clinically compatible case that is laboratory confirmed.

CHLAMYDIA TRACHOMATIS, GENITAL INFECTION

Clinical description

Clinical picture compatible with *Chlamydia trachomatis* infection, e.g. urethritis, epididymitis, cervicitis, acute salpingitis or other syndromes when sexually transmitted.

Laboratory criteria for diagnosis

— Isolation of *C. trachomatis* by culture from specimen of the uro-genital tract

— Demonstration of *C. trachomatis* in a clinical specimen from the uro-genital tract by detection of antigen or nucleic acid.

Case classification

Possible:	N.A.
Probable:	N.A.
Confirmed:	A case that is laboratory confirmed.

CHOLERA

Clinical description

Clinical picture compatible with cholera, e.g. watery diarrhoea and/or vomiting. Severity is variable.

Laboratory criteria for diagnosis

— Isolation of toxigenic (i.e. cholera toxin-producing) *Vibrio cholerae* O1 or O139 from stool or vomitus

— Demonstration of a specific anti-toxin and vibrocidal antibody response.

Case classification

Possible:	N.A.
Probable:	A clinically compatible case with an epidemiological link
Confirmed:	A clinically compatible case that is laboratory confirmed.

CRYPTOSPORIDIOSIS

Clinical description

Clinical picture compatible with cryptosporidiosis, characterised by diarrhoea, abdominal cramps, loss of appetite, nausea and vomiting.

Laboratory criteria for diagnosis

— Demonstration of *Cryptosporidium* oocysts in stool

— Demonstration of *Cryptosporidium* in intestinal fluid or small-bowel biopsy specimens

— Demonstration of *Cryptosporidium* antigen in stool.

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Case classification

Possible:	N.A.
Probable:	A clinically compatible case with an epidemiological link
Confirmed:	A case that is laboratory confirmed.

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DIPHTHERIA

Clinical description

Clinical picture compatible with either respiratory diphtheria, i.e. an upper respiratory tract illness characterised by an adherent membrane of the tonsils, pharynx or nose, in combination with sore throat and low grade fever, or non-respiratory diphtheria; i.e. an illness characterised by cutaneous, conjunctival, otic, genital or other types of ulcers.

Laboratory criteria for diagnosis

Isolation of diphtheria toxin-producing corynebacteria (typically *Corynebacterium diphtheriae* or *C. ulcerans*) from a clinical specimen.

Case classification

Possible:	N.A.
Probable:	a clinically compatible case.
Asymptomatic carriers:	asymptomatic carriers with toxigenic strains.
Confirmed:	a clinically compatible case that is laboratory confirmed with the isolation of a toxigenic strain of corynebacteria, or a clinically compatible case with an epidemiological link to a laboratory confirmed case.

It is to be noted that both respiratory and non-respiratory diphtheria cases with isolation of toxigenic strains should be reported, as should asymptomatic carriers with toxigenic strains, if they are detected. Cases with non-toxigenic *C. diphtheriae* or *C. ulcerans* should not be reported.

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ECHINOCOCCOSIS

Clinical description

Clinical picture compatible with echinococcosis, which may produce any of several clinical syndromes, varying with cyst size and location.

Laboratory criteria for diagnosis

Diagnosis by:

— Histopathology

— A combination of imaging techniques and serological tests (e.g. indirect haemagglutination, immunodiffusion, immunoblot assay).

Case classification

Possible:	N.A.
Probable:	N.A.
Confirmed:	A clinically compatible case that is laboratory confirmed.

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EHEC (infection with entero-haemorrhagic *Escherichia coli*)

Clinical description

Clinical picture compatible with EHEC infection, e.g. diarrhoea (often bloody) and abdominal cramps. Illness may be complicated by haemolytic uraemic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP).

Laboratory criteria for diagnosis

— Isolation of *E. coli* belonging to a sero-group known to cause enterohaemorrhagic disease

— Serological confirmation in patients with HUS or TTP

— For probable cases: detection of genes coding for St×1/St×2 production.

Case classification

Possible:	N.A.
Probable:	A laboratory confirmed isolate without clinical information or a case with clinical symptoms that has an epidemiological link
Confirmed:	A clinically compatible case that is laboratory confirmed.

GIARDIASIS

Clinical description

Clinical picture compatible with infection with *Giardia lamblia*, characterised by diarrhoea, abdominal cramps, bloating, weight loss, or malabsorption.

Laboratory criteria for diagnosis

— Demonstration of *G. lamblia* cysts in stool

— Demonstration of *G. lamblia* trophozoites in stool, duodenal fluid, or small-bowel biopsy

— Demonstration of *G. lamblia* antigen in stool.

Case classification

Possible:	N.A.
Probable:	A clinically compatible case that has an epidemiological link
Confirmed:	A case that is laboratory confirmed.

GONORRHOEA

Clinical description

Clinical picture compatible with gonorrhoea, e.g. urethritis, cervicitis, or salpingitis.

Laboratory criteria for diagnosis

— Isolation of *Neisseria gonorrhoeae* from a clinical specimen

— Detection of *N. gonorrhoeae* antigen or nucleic acid

— Demonstration of gram-negative intracellular diplococci in an urethral smear from a male.

Case classification

Possible:	N.A.
Probable:	N.A.
Confirmed:	A case that is laboratory confirmed.

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HAEMOPHILUS INFLUENZAE TYPE B, INVASIVE

Clinical description

Clinical picture compatible with invasive disease, e.g. bacteremia, meningitis, arthritis, epiglottitis, osteomyelitis or cellulitis.

Laboratory criteria for diagnosis

— Isolation of *Haemophilus influenzae* type B from normally sterile site
— Detection of *H. influenzae* nucleic acid from normally sterile site

For probable case:

— Detection of *H. influenzae* antigen from normally sterile site.

Case classification

Possible:	A case with clinical epiglottitis without any laboratory confirmation or with identification only from non-sterile site
Probable:	A clinically compatible case with antigen detection as above
Confirmed:	A clinically compatible case that is laboratory confirmed.

HEPATITIS, VIRAL

Clinical description

In symptomatic cases clinical picture compatible with hepatitis, e.g. discrete onset of symptoms and jaundice or elevated serum aminotransferase levels.

Hepatitis A, acute

Laboratory criteria for diagnosis

— IgM antibody to hepatitis A virus (anti-HAV) positive
— Detection of antigen in stool
— Detection of nucleic acid in serum.

Case classification

Possible:	N.A.
Probable:	A case that meets the clinical case definition and has an epidemiological link
Confirmed:	A case that meets the clinical case definition and is laboratory confirmed.

Hepatitis B, acute

Laboratory criteria for diagnosis

— IgM antibody to hepatitis B core antigen (anti-HBc) positive
— Detection of HBV nucleic acid in serum.

Case classification

Possible:	N.A.
Probable:	A case that is HbsAg positive and has a clinical picture compatible with an acute hepatitis
Confirmed:	A case that is laboratory confirmed.

Hepatitis C

Laboratory criteria for diagnosis

— Detection of HCV-specific antibodies

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— Detection of HCV nucleic acid from clinical samples.

Case classification

Possible:	N.A.
Probable:	N.A.
Confirmed:	A symptomatic case that is laboratory confirmed.

HIV INFECTION

(See under Acquired Immunodeficiency Syndrome above).

INFLUENZA

Clinical description

Clinical picture compatible with influenza, e.g. sudden onset of disease, cough, fever > 38º C, muscular pain and/or headache.

Laboratory criteria for diagnosis

— Detection of influenza antigen, or influenza virus specific RNA

— Isolation of influenza virus

— Demonstration of a specific serum antibody response to influenza A or B.

Case classification

Possible:	A clinically compatible case with an epidemiological link
Probable:	N.A.
Confirmed:	A clinical case that is laboratory confirmed.

LEGIONELLOSIS

Legionnaires' disease

Clinical description

Pneumonia

Pontiac fever

Clinical description

A self-limiting influenza-like illness characterised by fever, headache, myalgia and non-productive cough. Patients recover spontaneously without therapy after 2 to 5 days. No signs of pneumonia.

Laboratory criteria for diagnosis of legionellosis

— Isolation of any *Legionella* organism from respiratory secretion, lung tissue or blood

— Demonstration of a specific antibody response to *Legionella pneumophila* serogroup 1 or other serogroups or other *Legionella* species by the indirect immunofluorescent antibody test or by microagglutination

— Detection of specific *Legionella* antigen in urine using validated reagents

For probable case:

— A single high titre in specific serum antibody to *L. pneumophila* serogroup 1 or other serogroups or other *Legionella* species

— Detection of specific *Legionella* antigen in respiratory secretion or direct fluorescent antibody (DFA) staining of the organism in respiratory secretion or lung tissue using evaluated monoclonal reagents.

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Case classification

Possible:	N.A.
Probable:	A clinically compatible case that is tested by laboratory as probable (see above), or a clinically compatible case with an epidemiological link
Confirmed:	A clinically compatible case that is laboratory confirmed.

LEPTOSPIROSIS

Clinical description

Clinical picture compatible with leptospirosis, characterised by fever, headache, chills, myalgia, conjunctival suffusion, and less frequently by meningitis, rash, jaundice or renal insufficiency.

Laboratory criteria for diagnosis

— Isolation of *Leptospira* from a clinical specimen

— Demonstration of a specific increase in *Leptospira* agglutination titre

— Demonstration of *Leptospira* in a clinical specimen by immunofluorescence

— Detection of *Leptospir*a IgM antibody in serum.

Case classification

Possible:	N.A.
Probable:	N.A.
Confirmed:	A clinically compatible case that is laboratory confirmed.

LISTERIOSIS

Clinical description

Infection caused by *Listeria monocytogenes*, which may produce any of several clinical syndromes, including stillbirth, listeriosis of the newborn, meningitis, bacteremia or localised infections.

Laboratory criteria for diagnosis

— Isolation of *L. monocytogenes* from a normally sterile site (e.g. blood or cerebrospinal fluid or, less commonly, joint, pleural or pericardial fluid).

Case classification

Possible:	N.A.
Probable:	N.A.
Confirmed:	A clinically compatible case that is laboratory confirmed.

MALARIA

Clinical description

Clinical picture compatible with malaria, e.g. fever and common associated symptoms, which includes headache, back pain, chills, sweats, myalgia, nausea, vomiting, diarrhoea and cough.

Laboratory criteria for diagnosis

— Demonstration of malaria parasites in blood films

— Detection of *Plasmodium* nucleic acid.

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Case classification

Possible:	N.A.
Probable:	N.A.
Confirmed:	An episode of laboratory-confirmed malaria parasitemia in any person (symptomatic or asymptomatic).

MEASLES

Clinical description

Clinical picture compatible with measles, i.e. a generalised rash lasting >3 days and a temperature >38,0º C and one or more of the following: cough, coryza, Koplik's spots, conjunctivitis.

Laboratory criteria for diagnosis

— Detection of IgM antibodies against measles in the absence of recent vaccination

— Demonstration of a specific measles antibody response in absence of recent vaccination

— Detection of measles virus (not vaccine strains) in a clinical specimen.

Case classification

Possible:	A case diagnosed by a physician as measles
Probable:	A clinically compatible case
Confirmed:	A case that is laboratory confirmed or a clinically compatible case with an epidemiological link. A laboratory-confirmed case does not need to meet the clinical case definition.

MENINGOCOCCAL DISEASE

Clinical description

Clinical picture compatible with meningococcal disease, e.g. meningitis and/or meningococcemia that may progress rapidly to purpura fulminans, shock and death. Other manifestations are possible.

Laboratory criteria for diagnosis

— Isolation of *Neisseria meningitidis* from a normally sterile site (e.g. blood or cerebrospinal fluid (CSF) or, less commonly, joint, pleural or pericardial fluid)

— Detection of *N. meningitidis* nucleic acid from normally sterile site

— Detection of *N. meningitidis* antigen from normally sterile site

— Demonstration of gram-negative diplococci from normally sterile site by microscopy

For probable case:

— Single high titre of meningococcal antibody in convalescent serum.

Case classification

Possible:	N.A.
Probable:	A clinical picture compatible with invasive meningococcal disease without any laboratory confirmation, or with *N. meningitidis* identification from a non-sterile site, or with high levels of meningococcal antibody in convalescent serum
Confirmed:	A clinically compatible case that is laboratory confirmed. Note that asymptomatic carriers should not be reported.

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MUMPS

Clinical description

Clinical picture compatible with mumps, e.g. acute onset of uni- or bilateral tender, self-limited swelling of the parotid or other salivary gland, lasting >2 days, and without other apparent cause.

Laboratory criteria for diagnosis

— Detection of mumps IgM antibody
— Demonstration of specific mumps antibody response in absence of recent vaccination
— Isolation of mumps virus (not vaccine strains) from clinical specimen
— Detection of mumps nucleic acid

Case classification

Possible:	N.A.
Probable:	A case that meets the clinical case definition and is epidemiologically linked to a confirmed case
Confirmed:	A case that is laboratory confirmed.

PERTUSSIS (WHOOPING COUGH)

Clinical description

Clinical picture compatible with pertussis, e.g. a cough illness lasting at least 2 weeks with one of the following: paroxysms of coughing, inspiratory 'whoop' or post-tussive vomiting without other apparent cause.

Laboratory criteria for diagnosis

— Demonstration of a specific pertussis antibody response in absence of recent vaccination
— Detection of nucleic acid
— Isolation of *Bordetella pertussis* from clinical specimen.

Case classification

Possible:	A case that meets the clinical case definition
Probable:	A case that meets the clinical case definition and has an epidemiological link
Confirmed:	A case that is laboratory confirmed.

PLAGUE

Clinical description

The disease is characterized by fever, chills, headache, malaise, prostration and leukocytosis that manifests in one or more of the following principal clinical forms:

— regional lymphadenitis (bubonic plague),
— septicaemia without an evident bubo (septicemic plague),
— plague pneumonia,
— pharyngitis and cervical lymphadenitis.

Laboratory criteria for diagnosis

— Isolation of *Yersinia pestis* from a clinical specimen
— Demonstration of a specific antibody response to *Y. pestis* F1 antigen.

For probable case:

— Elevated serum antibody titre(s) to *Y. pestis* fraction 1 (F1) antigen (without documented specific change) in a patient with no history of plague vaccination
— Detection of F1 antigen in a clinical specimen by fluorescent assay.

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Case classification

Possible:	A clinically compatible case
Probable:	A clinically compatible case with probable laboratory results
Confirmed:	A clinically compatible case with confirmatory laboratory results.

POLIOMYELITIS, PARALYTIC

Clinical description

Clinical picture compatible with poliomyelitis, e.g. acute onset of a flaccid paralysis of one or more limbs with decreased or absent tendon reflexes in the affected limbs, without other apparent cause and without sensory or cognitive loss.

Laboratory criteria for diagnosis

— Isolation of poliovirus from a clinical specimen

— Detection of polio virus nucleic acid.

Case classification

Possible:	N.A.
Probable:	A case that meets the clinical case definition
Confirmed:	A case that meets the clinical case definition and is laboratory confirmed.

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Q-FEVER

Clinical description

A febrile illness accompanied by rigors, myalgia, malaise, and retrobulbar headache. Severe disease can include acute hepatitis, pneumonia, meningoencephalitis and abortion. Clinical laboratory findings may include elevated liver enzyme levels and abnormal film findings.

Laboratory criteria for diagnosis

— isolation of *Coxiella burnetii* from a clinical specimen,

— demonstration of a specific antibody response,

— demonstration of *C. burnetii* in a clinical specimen by detection of antigen or nucleic acid.

For probable cases: a single high titre of specific antibodies.

Case classification

Possible:	N.A.
Probable:	a clinically compatible case that fulfils the laboratory criteria for a probable case or has an epidemiological link.
Confirmed:	a laboratory confirmed case that is clinically compatible or has an epidemiological link.

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RABIES, HUMAN

Clinical description

Rabies is an acute encephalomyelitis that almost always progresses to coma or death within 10 days after the first symptom.

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Laboratory criteria for diagnosis

— Detection by direct fluorescent antibody of viral antigens in a clinical specimen (preferably the brain or the nerves surrounding hair follicles in the nape of the neck)
— Detection of rabies nucleic acid in clinical specimen
— Isolation (in cell culture or in a laboratory animal) of rabies virus from saliva, cerebrospinal fluid (CSF), or central nervous system tissue
— Identification of a rabies-neutralising antibody titre (complete neutralization) in the serum or CSF of an unvaccinated person.

Case classification

Possible:	A clinical compatible case without laboratory confirmation
Probable:	N.A.
Confirmed:	A clinically compatible case that is laboratory confirmed

RUBELLA

Clinical description

Clinical picture compatible with rubella, e.g. acute onset of generalized maculopapular rash and arthralgia/arthritis, lymphadenopathy, or conjunctivitis.

Laboratory criteria for diagnosis

— Detection of rubella IgM antibody in absence of recent vaccination
— Demonstration of a specific rubella antibody response in absence of recent vaccination
— Isolation of rubella virus in absence of recent vaccination
— Detection of rubella nucleic acid in clinical specimen.

Case classification

Possible:	A case that meets the clinical case definition
Probable:	A clinically compatible case that has an epidemiological link
Confirmed:	A clinically compatible case that is laboratory confirmed.

SALMONELLOSIS (NON-TYPHI, NON-PARATYPHI)

Clinical description

Clinical picture compatible with salmonellosis, e.g. diarrhoea, abdominal pain, nausea and sometimes vomiting. The organism may cause extraintestinal infections.

Laboratory criteria for diagnosis

— Isolation of *Salmonella* (non-typhi, non-paratyphi) from a clinical specimen.

Case classification

Possible:	N.A.
Probable:	A laboratory confirmed isolate without clinical information or, a case with clinical symptoms that has an epidemiological link
Confirmed:	A clinically compatible case that is laboratory confirmed.

SHIGELLOSIS

Clinical description

An illness of variable severity characterised by diarrhoea, fever, nausea, cramps, and tenesmus.

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Laboratory criteria for diagnosis

— Isolation of *Shigella sp*. from a clinical specimen.

Case classification

Possible:	N.A.
Probable:	A clinically compatible case with an epidemiological link
Confirmed:	A clinically compatible case that is laboratory confirmed.

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SMALLPOX

Clinical description

An illness with acute onset of fever over 38 ºC followed by a rash characterised by vesicles or firm pustules at the same stage of development without other apparent cause and with a predominantly centrifugal distribution.

Atypical presentations may include:

— haemorrhagic lesions,

— flat velvety lesions not appearing as typical vesicles nor progressing to pustules.

Laboratory criteria for diagnosis

Isolation of smallpox (*Variola*) virus from a clinical specimen.

Polymerase chain reaction (PCR) identification of *Variola* DNA in a clinical specimen, followed by sequencing.

Negative-stain Electron microscopy (EM) identification of *Variola* virus in a clinical specimen.

Case classification

Possible:	a clinically compatible case A case that has an atypical presentation and has an epidemiological link to confirmed or probable cases.
Probable:	a clinically compatible case with either identification of orthopox virus by EM or PCR, or an epidemiological link to other probable or confirmed cases.
Confirmed:	for an initial case, a clinically compatible case with laboratory confirmation by EM and PCR, followed by sequencing.

During an outbreak, a clinically compatible case with an epidemiological link and, where possible, laboratory confirmation by either EM or PCR.

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STREPTOCOCCUS PNEUMONIAE, INVASIVE DISEASE

Clinical description

Steptococcus pneumoniae causes many clinical syndromes, depending on the site of infection (e.g. acute otitis media, pneumonia, bacteremia, or meningitis).

Laboratory criteria for diagnosis

— Isolation of *S. pneumoniae* from a normally sterile site (e.g. blood, cerebrospinal fluid, or, less commonly, joint, pleural or pericardial fluid)

— Detection of *S. pneumoniae* nucleic acid from a normally sterile site

For probable case:

— Detection of *S. pneumoniae* antigen from a normally sterile site.

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Case classification

Possible:	A clinically compatible case without any laboratory confirmation, or with identification from a non-sterile site
Probable:	A clinically compatible case that is antigen positive
Confirmed:	A clinically compatible case that is laboratory confirmed.

SYPHILIS

Syphilis, primary

Clinical description

A stage of infection with *Treponema pallidum* characterised by one or more chancres (ulcers). Chancres might differ considerably in clinical appearance.

Laboratory criteria for diagnosis

— Detection of specific IgM by EIA

— Demonstration of *T. pallidum* in clinical specimens by dark field microscopy, direct fluorescent antibody (DFA-TP) or equivalent methods

For probable case:

— A reactive serologic test (nontreponemal: Venereal Disease Research Laboratory (VDRL) or rapid plasma reagin (RPR); treponemal: fluorescent treponemal antibody absorbed (FTA-ABS) or microhemagglutination assay for antibody to *T. pallidum* (MHA-T]).

Case classification

Possible:	N.A.
Probable:	A clinically compatible case with one or more ulcers (chancres) consistent with primary syphilis and any reactive serologic test
Confirmed:	A clinically compatible case that is laboratory confirmed.

Syphilis, secondary

Clinical description

A stage of infection caused by *T. pallidum* and characterised by localised or diffuse mucocutaneous lesions, often with generalised lymphadenopathy. The primary chancre may still be present.

Laboratory criteria for diagnosis

— Demonstration of *T. pallidum* in clinical specimens by dark field microscopy, direct fluorescent antibody (DFA-TP) or equivalent methods

For probable case:

— A reactive serologic test (nontreponemal: Venereal Disease Research Laboratory (VDRL)

— Rapid plasma reagin (RPR); treponemal: fluorescent treponemal antibody absorbed (FTA-ABS)

— Microhaemagglutination assay for antibody to *T. pallidum* (MHA-TP).

Case classification

Possible:	N.A.
Probable:	A clinically compatible case with any respective serologic test
Confirmed:	A clinically compatible case that is laboratory confirmed.

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Syphlis, latent

Clinical description

A stage of infection caused by *T. pallidum* in which organisms persist in the body of the infected person without causing symptoms or signs.

Laboratory criteria for diagnosis

Demonstration of a positive reaction with a specific EIA but negative for laboratory test for infectious syphilis (see primary or secondary syphilis).

Case classification

Possible:	N.A.
Probable:	No clinical signs or symptoms of syphilis and a positive laboratory test as above
Confirmed:	N.A.

TETANUS

Clinical description

Clinical picture compatible with tetanus, e.g. acute onset of hypertonia and/or painful muscular contractions (usually of the muscles of the jaw and neck) and generalised muscle spasms without other apparent medical cause.

Laboratory criteria for diagnosis

— Detection of tetanus toxoid antibody in an unvaccinated and untreated patient

— Demonstration of a specific tetanus toxoid antibody response.

Case classification

Possible:	N.A.
Probable:	N.A.
Confirmed:	A clinically compatible case.

TOXOPLASMOSIS

Clinical description

A protozoan disease, which presents with an acute illness with one or more of the following: lymphadenopathy, encephalitis, chorioretinitis, disfunction of the central nervous system. Congenital infections may also occur with hydrocephalus, microcephalus, intracerebral calcification, convulsions, cerebral retardation.

Laboratory criteria for diagnosis

— Demonstration of a specific *toxoplasma* antibody response

— Demonstration of the agent in body tissues or fluids or isolation in animals or cell culture

— Detection of *toxoplasma* nucleic acid.

Case classification

Possible:	N.A.
Probable:	N.A.
Confirmed:	A clinically compatible case that is laboratory confirmed.

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TRICHINOSIS

Clinical description

A disease caused by ingestion of *Trichinella* larvae. The disease has variable clinical manifestations. Common signs and symptoms among symptomatic persons include eosinophilia, fever, myalgia and periorbital œdema.

Laboratory criteria for diagnosis

— Demonstration of *Trichinella* larvae in tissue obtained by muscle biopsy

— Demonstration of a specific *Trichinella* antibody response.

Case classification

Possible:	N.A.
Probable:	A clinically compatible case with an epidemiological link
Confirmed:	A clinically compatible case that is laboratory confirmed.

TUBERCULOSIS

Clinical criteria

— A clinician's judgement that clinical and/or radiological signs and/or symptoms are compatible with tuberculosis

and

— a clinician's decision to treat the patient with a full course of anti-tuberculosis therapy.

Laboratory criteria

— Isolation of *Mycobacterium tuberculosis* complex (except *M. bovis* BCG) from any clinical specimen by culture

— Evidence of acid-fast bacilli (AFB) at microscopic examination of spontaneous or induced sputum.

Classification according to laboratory criteria

Definite

A case with isolation of *M. tuberculosis* complex (except *M. bovis* BCG) from any clinical specimen. In countries where culture is not routinely available, a case with sputum smear examinations positive for AFB is also considered to be a definite case.

Other than definite

A case that meets the clinical criteria above but does not meet the laboratory criteria of a definite case.

Classification according to site of disease

Pulmonary tuberculosis

Tuberculosis of the lung parenchyma or the tracheo-bronchial tree.

Extrapulmonary tuberculosis

Tuberculosis affecting any site other than pulmonary as defined above.

Classification according to previous anti-tuberculosis treatment

Never treated

A case which never received a treatment for active tuberculosis in the past or which received anti-tuberculosis drugs for less than one month.

Previously treated

A case which was diagnosed with active tuberculosis in the past and received anti-tuberculosis drugs (excluding preventive therapy) for at least one month.

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TULARAEMIA

Clinical description

Clinical picture compatible with one of the different forms of tularaemia:

— ulceroglandular (cutaneous ulcer with regional lymphadenopathy),

— glandular (regional lymphadenopathy with no ulcer),

— oculoglandular (conjunctivitis with preauricular lymphadenopathy),

— oropharyngeal (stomatitis or pharyngitis or tonsillitis and cervical lymphadenopathy),

— intestinal (intestinal pain, vomiting, and diarrhoea),

— pneumonic (primary pneumonic disease),

— typhoidal (febrile illness without early localising signs and symptoms).

Laboratory criteria for diagnosis

— Isolation of *Francisella tularensis* from a clinical specimen,

— demonstration of a specific antibody response.

For probable cases:

— a single high titre,

— detection of *F. tularensis* in a clinical specimen by fluorescent assay.

Case classification

Possible:	N.A.
Probable:	a clinically compatible case that fulfils the laboratory criteria for a probable case or has an epidemiological link.
Confirmed:	a clinically compatible case that is laboratory confirmed.

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TYPHOID/PARATYPHOID FEVER

Clinical description

An illness caused by *Salmonella typhi or paratyphii* that is often characterised by insidious onset of sustained fever, headache, malaise, anorexia, relative bradycardia, constipation or diarrhoea and nonproductive cough. However, many mild and atypical infections occur.

Laboratory criteria for diagnosis

— Isolation of *S. typhi or paratyphii* from blood, stool or other clinical specimen.

Case classification

Possible:	N.A.
Probable:	A laboratory confirmed isolate without clinical information or, a case with clinical symptoms with an epidemiological link
Confirmed:	A clinically compatible case that is laboratory confirmed.

VARIANT CREUTZFELDT–JAKOB'S DISEASE

Clinical description

I. *History*

— Progressive neuropsychiatric disorder,

— Duration of illness > 6 months,

— Routine investigation do not suggest an alternative diagnosis,

— No history of potential iatrogenic exposure.

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II. *Clinical features*

— Early psychiatric symptoms,

— Persistent painful sensory symptoms,

— Ataxia,

— Myoclonus or chorea or dystonia,

— Dementia.

Laboratory criteria for diagnosis

— EEG does not show typical appearance of classical CJD (or no EEG performed)

— Bilateral pulvinar high signal on MRI scan

— Characteristic neuropathological and immunopathological findings.

Case classification

Possible:	N.A.
Probable:	I and 4/5 of clinical features and EEG does not show typical appearance of classical CJD (or no EEG performed) and Bilateral pulvinar high signal on MRI scan
	I and positive tonsil biopsy
Confirmed:	Progressive neuropsychiatric disorder and neuropathological confirmation of diagnosis of vCJD.

VIRAL HAEMORRHAGIC FEVERS

Ebola/Marburg fever

Clinical description

Begins with acute fever, diarrhoea that can be bloody and vomiting. Headache, nausea, and abdominal pain are common. Haemorrhagic manifestations may follow. Some patients may also show a maculopapular rash on the trunk.

Laboratory criteria for diagnosis

— Positive virus isolation

— Positive skin biopsy (immunohistochemistry)

— Detection of Ebola/Marburg virus nucleic acid

— Positive serology, which may appear late in the course of the disease.

Case classification

Possible:	N.A.
Probable:	A clinically compatible case with an epidemiological link
Confirmed:	A clinically compatible case that is laboratory-confirmed.

Lassa fever

Clinical description

An illness of gradual onset with malaise, fever, headache, sore throat, cough, nausea, vomiting, diarrhoea, myalgia and chest pain. Haemorrhagic manifestations may follow.

Laboratory criteria for diagnosis

— Virus isolation

— Positive skin biopsy (immunohistochemistry)

— Detection of Lassa virus nucleic acid

— Positive serology, which may appear late in the course of the disease.

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Case classification

Possible:	N.A.
Probable:	A clinically compatible case with an epidemiological link
Confirmed:	A clinically compatible case that is laboratory-confirmed.

Congo-Crimean haemorrhagic fever

Clinical description

An illness of gradual onset with acute high fever, chills, myaliga, nausea, anorexia, vomitting, headache and backache. Haemorrhagic manifestations may follow.

Laboratory criteria for diagnosis

— Virus isolation

— Detection of CCHF virus nucleic acid

— Positive serology, which may appear late in the course of the disease.

Case classification

Possible:	N.A.
Probable:	A clinically compatible case with an epidemiological link
Confirmed:	A clinically compatible case that is laboratory-confirmed.

YELLOW FEVER

Clinical description

An illness characterised by acute onset and constitutional symptoms followed by a brief remission, a recurrence of fever, hepatitis, albuminuria, and in some instances, renal failure, shock and generalised hæmorrhages.

Laboratory criteria for diagnosis

— Demonstration of a specific yellow fever antibody response in a patient who has no history of recent yellow fever vaccination and where cross-reactions to other flaviviruses have been excluded

— Virus isolation

— Detection of yellow fever antigen

— Detection of yellow fever nucleic acid.

Case classification

Possible:	N.A.
Probable:	A clinically compatible case with an epidemiological link
Confirmed:	Any clinically compatible case that is laboratory-confirmed.

YERSINIOSIS

Clinical description

An illness of variable severity characterised by diarrhoea, fever, nausea, cramps and tenesmus.

Laboratory criteria for diagnosis

— Isolation of *Yersinia enterocolitica or pseudotubeculosis* from a clinical specimen.

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Case classification

Possible:	N.A.
Probable:	A clinically compatible case with an epidemiological link
Confirmed:	A case that is laboratory confirmed.