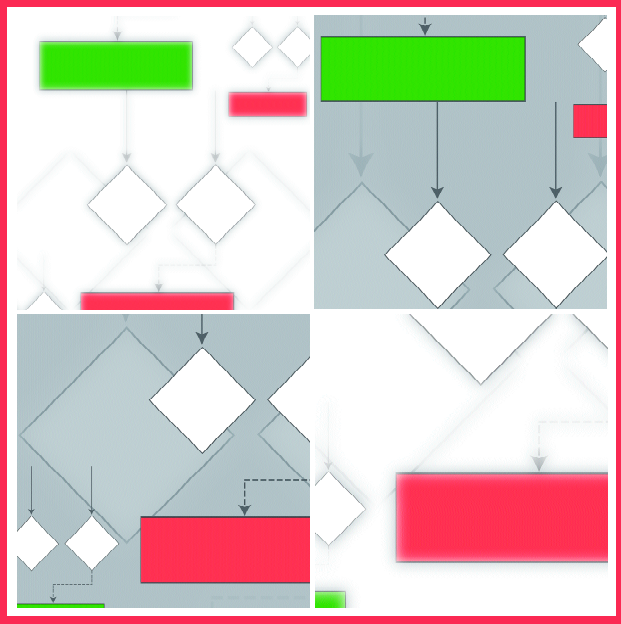
NSW HEALTH

Laboratory Notification Flowcharts

March 2006

version 1.3



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State Health Publication.
SHPN (PHD) 060076
ISBN 0 7347 39051 6

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March 2006

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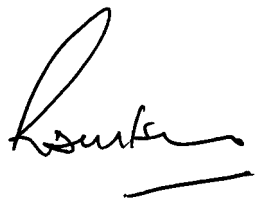
Foreword

Under the NSW Public Health Act 1991, there are 50 Scheduled Medical Conditions which NSW laboratories are required to notify to the NSW Health Department. In recognition of the public health benefits of ensuring receipt of these notifications in a timely manner, and the necessity for a well documented and explicit set of rules for the generation of a notification, the Population Health Division, NSW Health Department, began the eNotification project in November 2004. The eNotification (electronic pathology laboratory notification) project aims to replace paper-based notification from the top twenty laboratories, by volume of notification, with electronic notification.

The first step in developing a robust eNotification system in NSW was considered to be the development and documentation of detailed specifications for laboratory notification triggers (based on existing case definitions) and a set of business rules detailing when to report, how to report and who reports.

A working group was established (the NSW eNotification Project – Business Rules Working Group) with representation from the Public Health Laboratory Network (PHLN), private and public pathology laboratories, the Royal College of Pathologists of Australasia, Australian Government Department of Health and Ageing, NSW Public Health Units and the NSW Health Department. The Working Group spent several months reviewing each of the PHLN and Communicable Diseases Network of Australia (CDNA) case definitions (for the NSW notifiable diseases) and translating the case definitions into flowcharts depicting the disease-specific internal laboratory processes for identifying evidence of infection and points within the process where notification of a result to the health authorities would be expected. (Submissions have also been prepared for the PHLN and CDNA case definition working groups outlining instances where the NSW eNotification Project – Business Rules Working Group considered revision of the case definition was required.) The Working Group has agreed to continue to meet to maintain and review the flowcharts and triggers for NSW Health.

Should you have comments on any aspect of the document we would be most happy to receive them at ndd@doh.health.nsw.gov.au. Similarly, should you consider the documents to be useful for similar activities within your organisation or jurisdiction, you are welcome to use any part of the document, with appropriate acknowledgements. Should you make any amendments to the flowcharts for use in your organisation or jurisdiction we would be keen to hear about this since it may also inform future revisions in NSW.



Associate Professor Roger Wilson
Chair, NSW eNotification Project – Business Rules Working Group

March 2006

About this document

Under the NSW Public Health Act 1991, there are 50 Scheduled Medical Conditions which NSW laboratories are required to notify to the NSW Health Department.

In recognition of the public health benefits of ensuring receipt of these notifications in a timely manner, and the necessity for a well documented and explicit set of rules for the generation of a notification, the NSW eNotification (electronic pathology laboratory notification) Project was commenced in November 2004.

The first step in developing a robust eNotification system in NSW was considered to be the development and documentation of detailed specifications for laboratory notification triggers (based on existing case definitions) and a set of business rules detailing when to report, how to report and who reports.

This document aims to record the business rules and triggers for laboratory initiated notification of Scheduled Medical Conditions, whether the notification is delivered electronically or by conventional means. A companion document, Public Health Action Flowcharts, which outlines the public health interventions that accompany notification of a Scheduled Medical Condition, is under development.

The triggers for notification of laboratory results shown in the flowcharts are defined by surveillance case definitions for notifiable diseases developed by the Communicable Diseases Network of Australia (CDNA). The CDNA surveillance case definitions are based on laboratory case definitions produced by the Public Health Laboratory Network (PHLN), which describe diagnostic tests available for each notifiable disease and their performance characteristics. These documents may be accessed on the CDNA and PHLN websites:
http://www.health.gov.au/internet/wcms/publishing.nsf/Content/Case+definitions-1; and
http://www.health.gov.au/internet/wcms/publishing.nsf/Content/cda-cdna-phln-phln.htm

Laboratory best practice recommends that the case definitions and therefore, the triggers, are most appropriate when certain criteria apply, namely:

- The test has been performed in the context of an appropriate clinical setting and illness;
- The utility of the test should be known in the population from which the test sample is derived;
- The specific test is within the scope of the performing laboratory's accreditation with the National Association of Testing Authorities (NATA); and
- Tests, particularly, but not only, nucleic acid tests (NATs), have appropriately documented validation.

However, ALL laboratory results that meet the triggers outlined in this document should be notified to the NSW Health Department.

Using the flowcharts

The flowcharts are consistently arranged by category or activity. That is:

Specimen	For the majority of conditions any clinical specimen is acceptable. However, if the case definition requires a certain specimen, or the particular test is validated only for a particular type of specimen, these details are specified.
Testing	The types of laboratory tests currently being used, or those that are likely to be used in the near future, for the identification of infection.
Trigger	The laboratory result, or results, that initiate notification of a Scheduled Medical Condition.
Validation	Only trigger events validated by a senior laboratory staff member should be notified.
Report Generation	An individual report (eNotification message) is generated at each level of evidence of disease (for additional information see explanation below).
Evidence of Disease	Indicates the level of evidence that an individual laboratory result, generated in an appropriate clinical setting, signifies a specific condition or disease, from a public health perspective.
Notes	Additional information provided where a particular issue requires clarification or emphasis.

Evidence of disease

Although laboratory results in isolation can only provide evidence of infection not disease, the term **'evidence of disease'** has been used throughout this document assuming that the majority of these results will be generated in the context of clinical symptoms. It is the nature of the laboratory results, and the associated evidence of disease, that initiates the public health response. Under these circumstances the following definitions apply:

Presumptive Laboratory Result –represents the initial screening or preliminary identification of organisms, most commonly performed in the primary laboratory.

Confirmed Laboratory Result - provides the definitive result following preliminary testing and is most commonly used when presumptively identified organisms are ratified by further definitive testing.

Suggestive Evidence of Disease – these test results are often not fully specific for the disease being investigated. Additional testing is usually required to confirm the diagnosis. This category includes nucleic acid tests (NAT) which detect the presence of genes similar to those found in related non-pathogens. For example, most PCR assays for *Neisseria gonorrhoeae* target genes that, occasionally, are found in non-pathogenic *Neisseria* species. A positive result is therefore only suggestive of infection with *N. gonorrhoeae* and requires supplementary testing.

Definitive Evidence of Disease – these are test results, which on their own are good evidence of a specific diagnosis. For example, PCR tests for *Bordetella pertussis* detect the toxin gene, which is found only in this organism. A positive result in this instance is strong evidence of infection.

Further clarification, and colour coding, around the type of results generated by the laboratory (presumptive OR confirmed) and the type of evidence of disease (suggestive OR definitive) has been incorporated into these flowcharts.

As a consequence there are now three variations: *'Presumptive Laboratory Result - Suggestive Evidence of Disease', 'Confirmed Laboratory Result - Suggestive Evidence of Disease' and 'Confirmed Laboratory Result - Definitive Evidence of Disease'*, where the disease is seen in a public health context.

There is also a clear pathway for reporting additional information that rules out the notifiable condition (eg a non-toxigenic isolate), *'Confirmed Laboratory Result – Not Indicative of Infection'*.

Dotted lines indicate a test currently being used for research purposes or one that is not widely used.

Presumptive Laboratory Result
Suggestive Evidence of Disease
PHONE NOTIFICATION

Confirmed Laboratory Result
Suggestive Evidence of Disease
PHONE NOTIFICATION

Confirmed Laboratory Result
Definitive Evidence of Disease
PHONE NOTIFICATION

Confirmed Laboratory Result
Not Indicative of Disease
PHONE NOTIFICATION

Glossary

Certain terminology used throughout this document is defined below.

Detection of IgM: This is usually sufficient to indicate recent infection. However following some infections - such as those due to the alphaviruses and flaviviruses - IgM persists for months to years, and may only provide suggestive evidence of recent infection. IgM can also cross-react, particularly with flavivirus infections. False positive IgM reactions are a recognised problem in serological diagnosis, and laboratories should have ensured that their methods and protocols take this in to account. An IgG level should always be measured as this may help to interpret the significance of a single IgM. The presence of IgM in the absence of IgG suggests either early infection, in which case it should be possible to demonstrate seroconversion if a second serum is collected, or a false positive if it remains absent. In general, a single IgM does not constitute definitive evidence of infection and confirmatory testing (such as neutralisation assays in titration series) should be performed.

Seroconversion – a change from IgG negative to IgG positive, generally between acute and convalescent samples. Identification of seroconversion may be used for confirming recent infection, using tests that do not quantify the antibody levels. This includes most enzyme immunoassay, particle agglutination, immunofluorescent antibody and latex agglutination tests as performed routinely. Results are valid only if both sera have been tested in parallel in the same laboratory.

Significant increase in antibody level or titre - this is generally confined to tests that use titrations in two-fold dilutions, in which a four-fold increase is regarded as significant. For enzyme immunoassay tests that are not titred, it may be possible to establish changes in absorbance that may be regarded as significant. This has to be determined and validated for individual tests, and should be approached with caution. Results are valid only if tested in parallel in the same laboratory.

Single high titre - generally the level constituting a single high titre is not stated as this may vary between tests and laboratories. In these cases the criterion for high titre needs to be evaluated and validated from local data and experience. If possible, a second serum should be collected and tested in parallel with the first serum to monitor changes in antibody level.

Supplementary testing – this type of analysis often provides further information about an isolate for public health purposes. Examples of supplementary testing are toxigenicity testing, serotyping and phage typing and can include the use of an alternative serological method to provide additional information about an antibody response.

Specialist laboratory – a laboratory that is able to provide testing not normally performed in routine diagnostic laboratories owing to a lack of appropriate expertise associated with a specific testing methodology or organism, unavailability of reagents, or a lack of specific funding mechanisms. ‘Specialised’ tests include, but are not limited to, salmonella serotyping and phagetyping, toxin testing and serology for diagnosis of disease caused by individual flaviviruses. The process for deciding which laboratories are specialist laboratories is an issue outside the scope of this document.

Contributors

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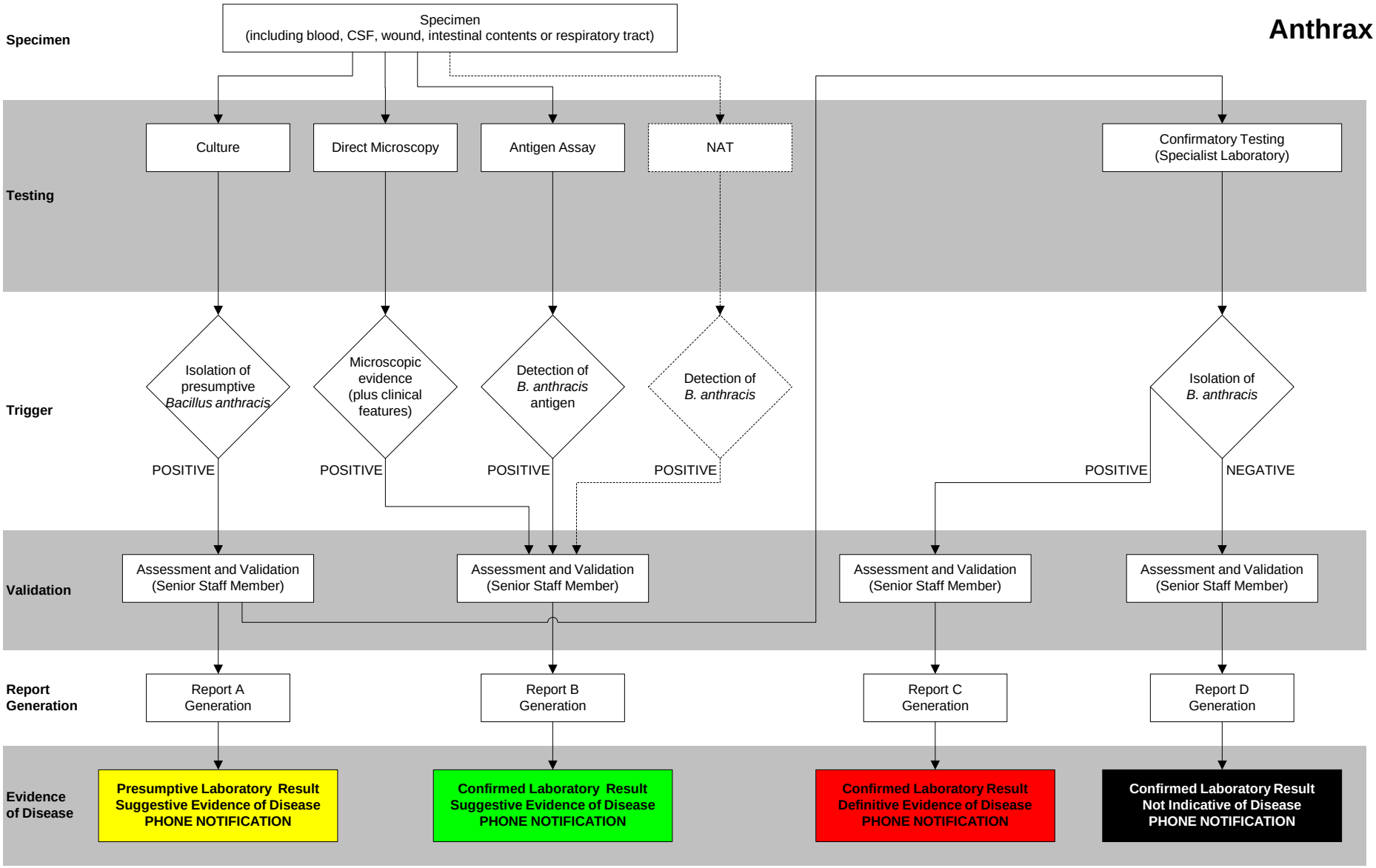
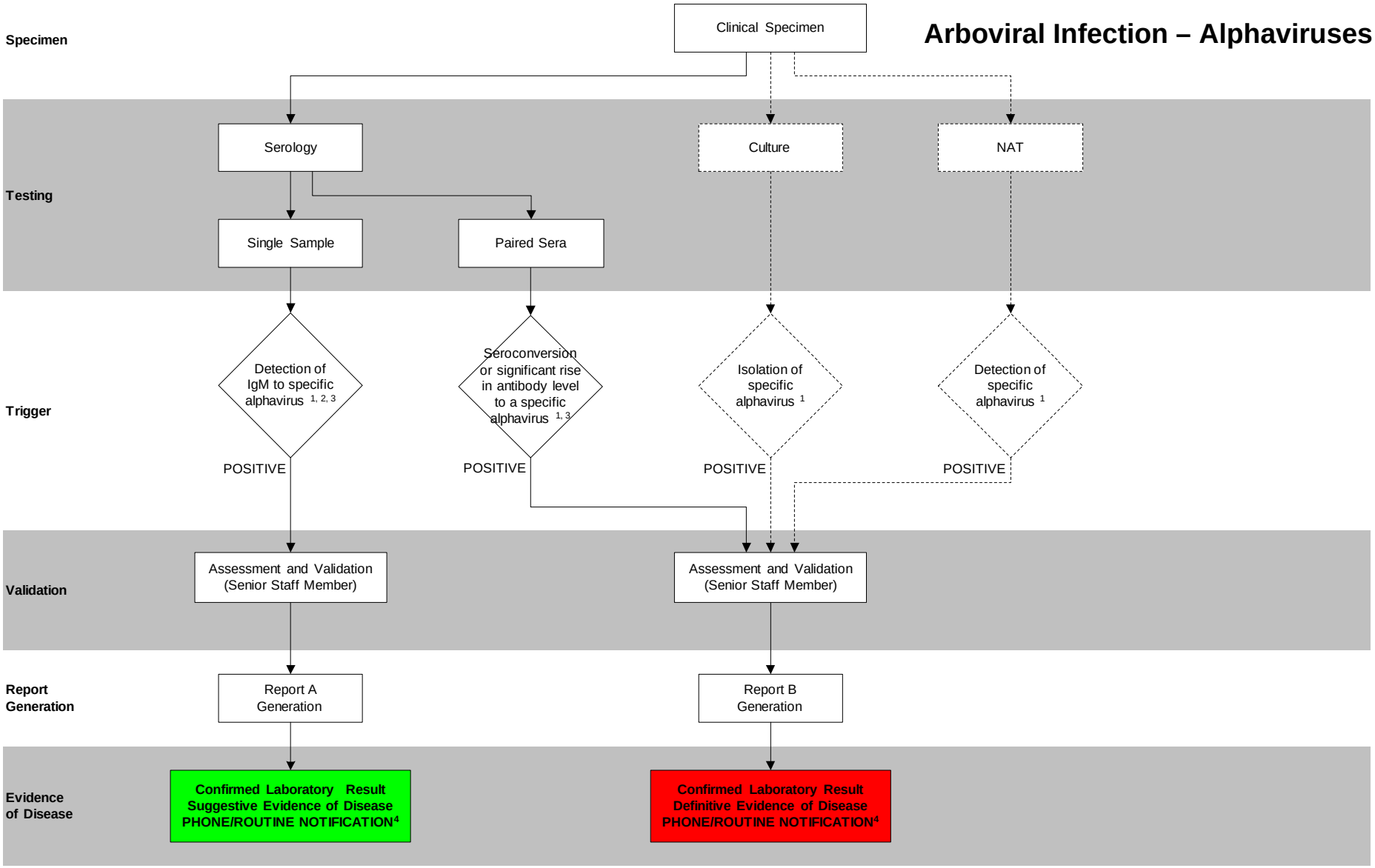
Anthrax


Specimen
Specimen
(including blood, CSF, wound, intestinal contents or respiratory tract)
Testing
Culture
Direct Microscopy
Antigen Assay
NAT
Confirmatory Testing
(Specialist Laboratory)
Trigger
Isolation of presumptive Bacillus anthracis
Microscopic evidence (plus clinical features)
Detection of B. anthracis antigen
Detection of B. anthracis
Isolation of B. anthracis
POSITIVE
POSITIVE
POSITIVE
POSITIVE
POSITIVE
NEGATIVE
Validation
Assessment and Validation (Senior Staff Member)
Assessment and Validation (Senior Staff Member)
Assessment and Validation (Senior Staff Member)
Assessment and Validation (Senior Staff Member)
Report Generation
Report A Generation
Report B Generation
Report C Generation
Report D Generation
Evidence of Disease
Presumptive Laboratory Result
Suggestive Evidence of Disease
PHONE NOTIFICATION
Confirmed Laboratory Result
Suggestive Evidence of Disease
PHONE NOTIFICATION
Confirmed Laboratory Result
Definitive Evidence of Disease
PHONE NOTIFICATION
Confirmed Laboratory Result
Not Indicative of Disease
PHONE NOTIFICATION
Notes

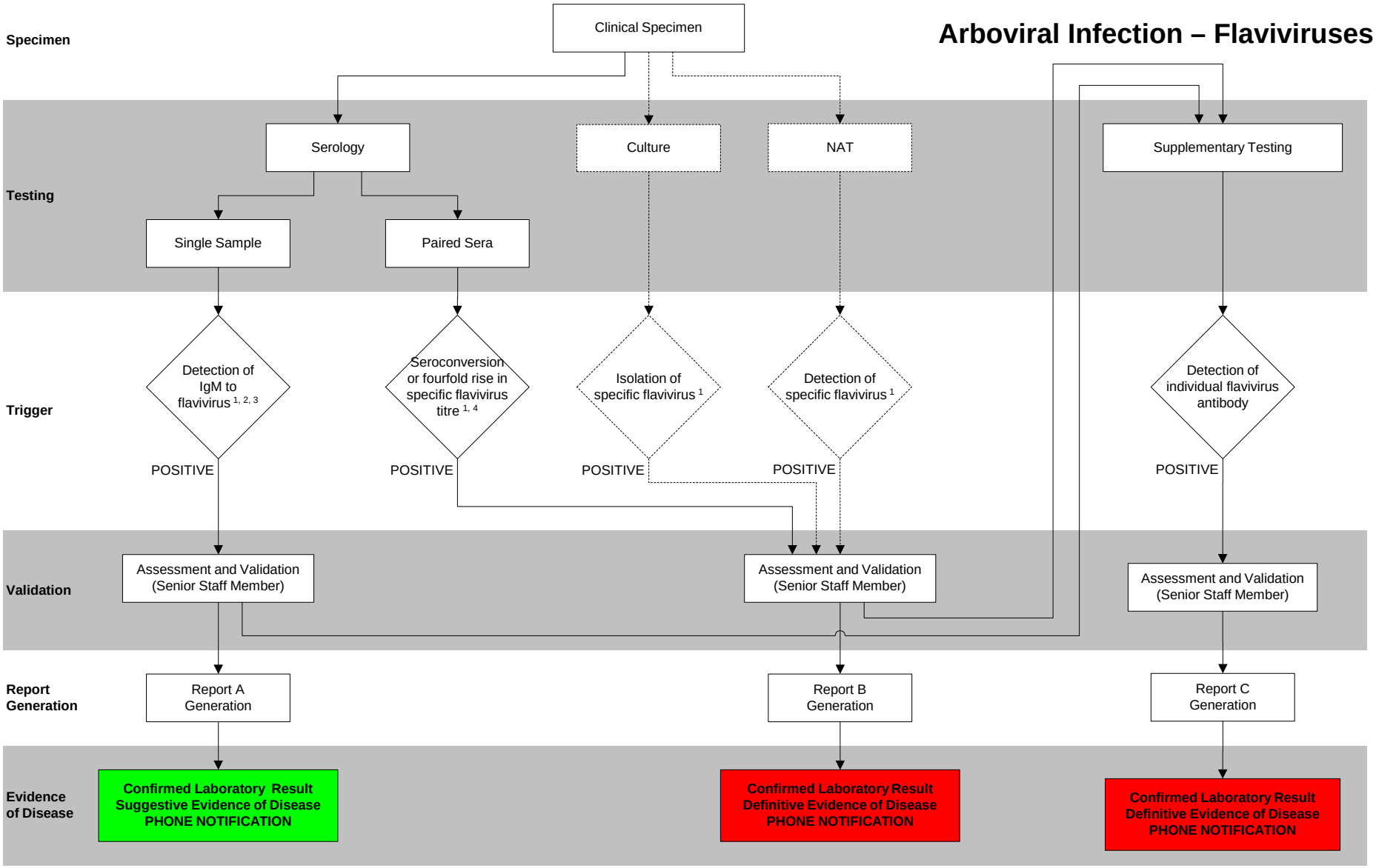
Arboviral Infection – Alphaviruses



Notes

1 A specific virus can be assigned if the antibody is shown to be limited to an individual virus by neutralisation, or another specific test
2 IgM can persist in some cases for years, so a single IgM result should be considered in the context of the clinical setting and may not be definitive evidence of disease
3 Seroconversion or significant rise in antibody level to a specific alphavirus, between acute and convalescent phase sera (tested in parallel at the same laboratory)
4 **PHONE** public health priority for alphaviruses acquired in a low/no risk area, **ROUTINE** for other cases

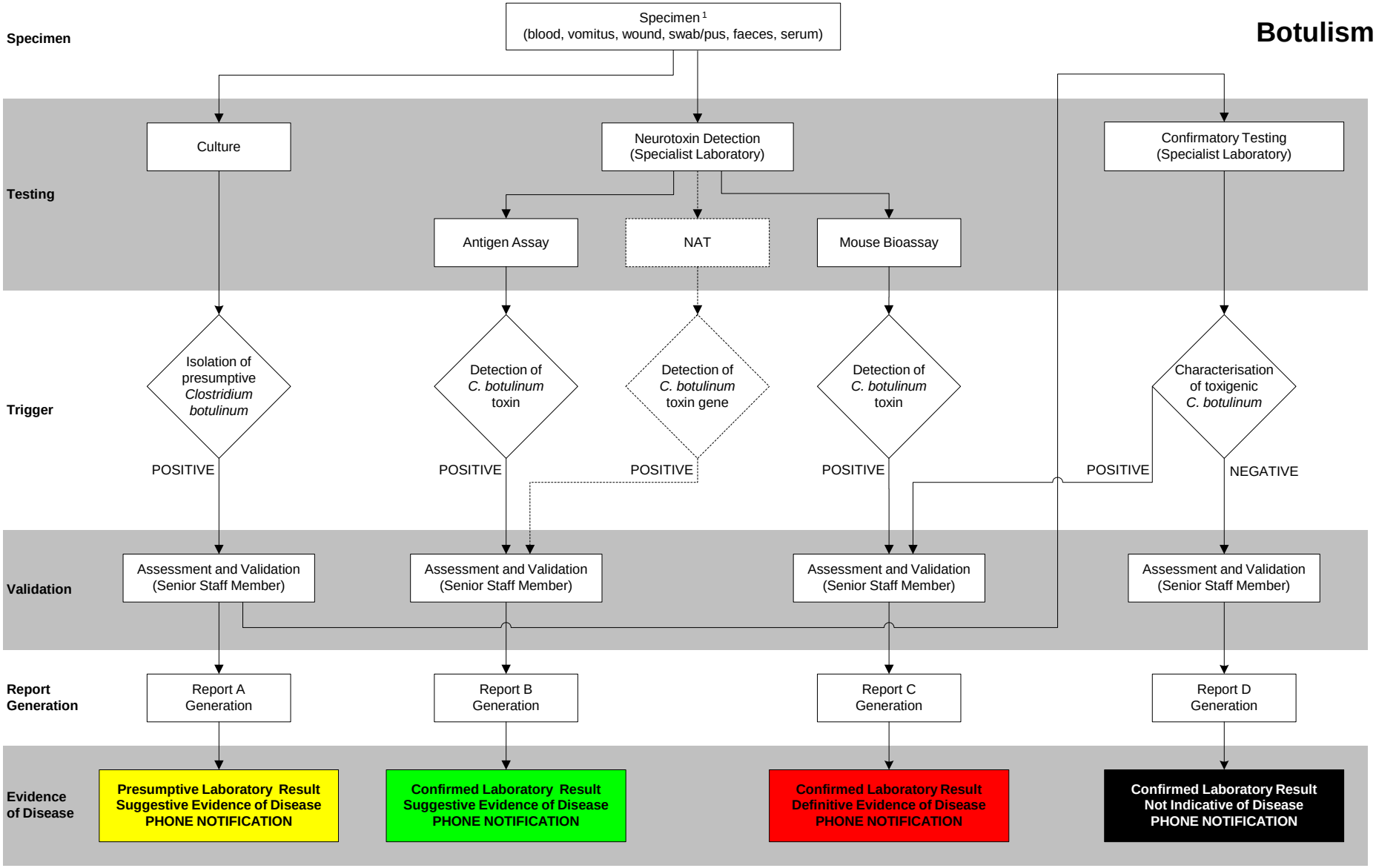
Arboviral Infection – Flaviviruses



Notes

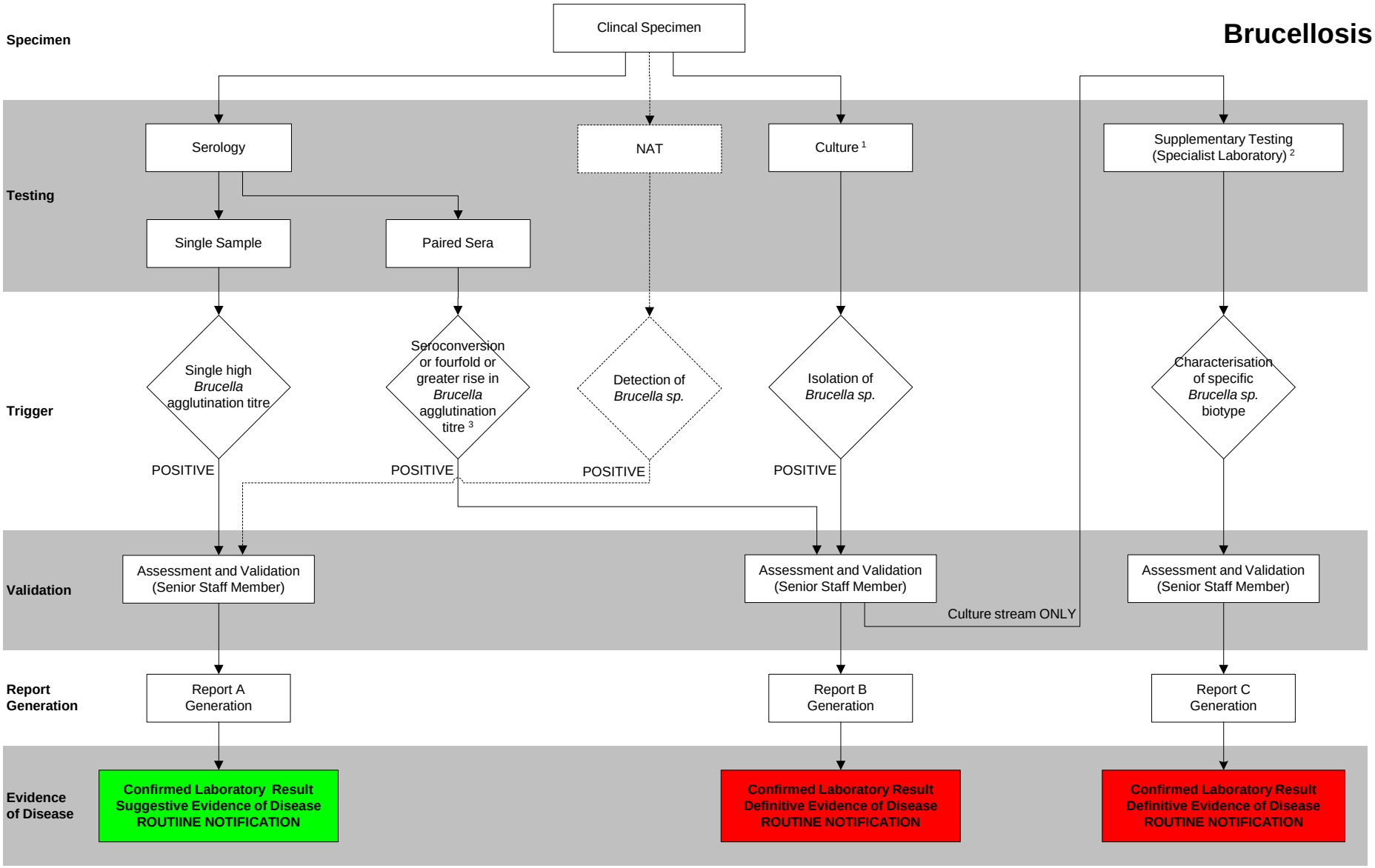
1 A specific virus can be assigned if the antibody is shown to be limited to an individual virus by neutralisation, or another specific test
2 IgM can persist in some cases for years, so a single IgM result should be considered in the context of the clinical setting and may not be definitive evidence of disease
3 Also includes IgM in CSF
4 Seroconversion or significant rise in antibody level to a specific alphavirus, between acute and convalescent phase sera (tested in parallel at the same laboratory)

Botulism



Notes 1 Detection of Clostridium botulinum or neurotoxin in implicated food should also be notified in line with CDNA/PHLN case definitions

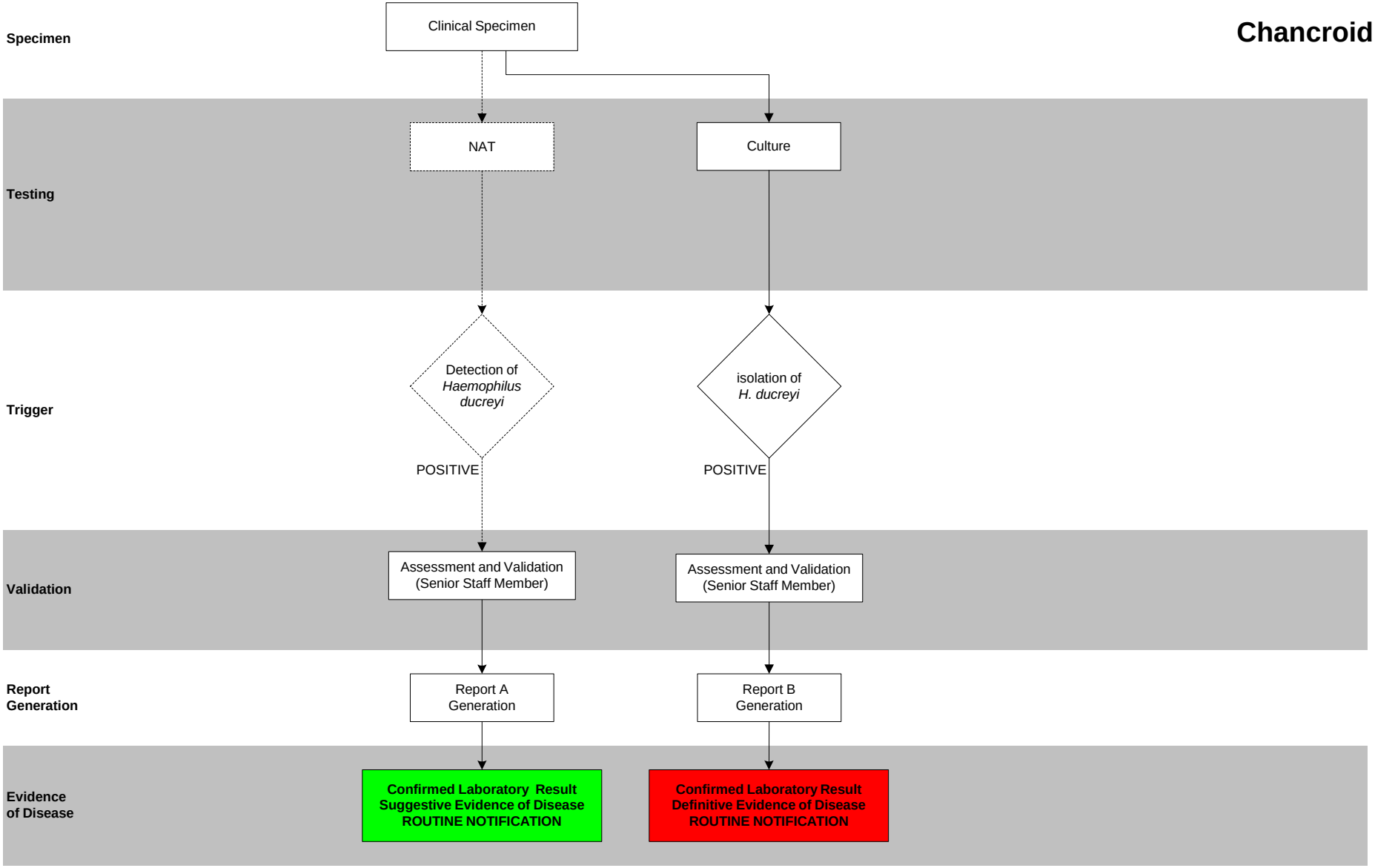
Brucellosis



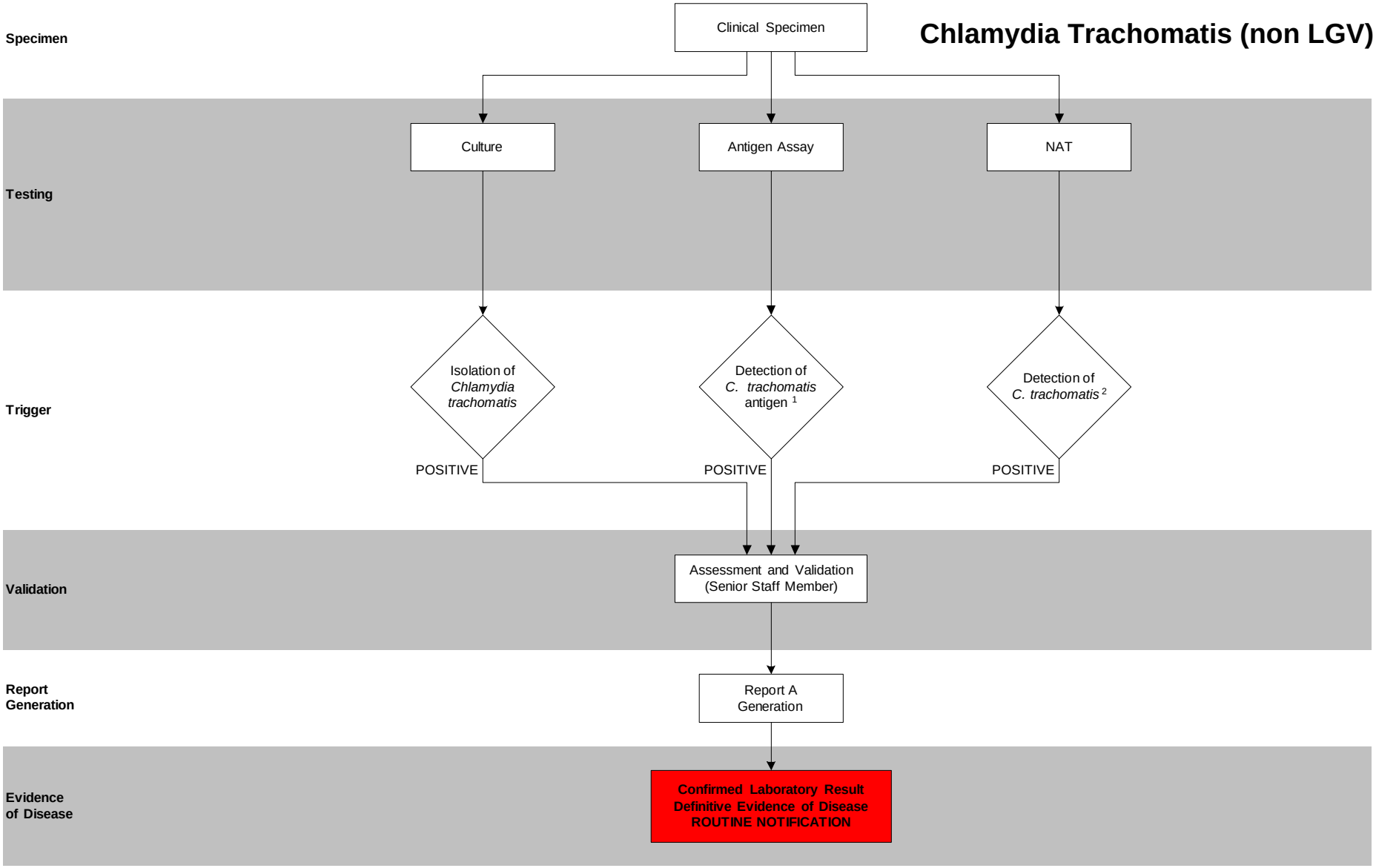
Notes

1 Testing perfomed at a specialist laboratory, for safety reasons non-specialist laboratories should avoid culture
2 All Brucella isolates should be referred to a specialist laboratory for further characterisation
3 Seroconversion or fourfold or greater rise in *Brucella* agglutination titre between acute and convalescent phase sera (tested in parallel at the same laboratory)

Chancroid


Specimen
Clinical Specimen
Testing
NAT
Culture
Trigger
Detection of *Haemophilus ducreyi*
isolation of *H. ducreyi*
POSITIVE
POSITIVE
Validation
Assessment and Validation (Senior Staff Member)
Assessment and Validation (Senior Staff Member)
Report Generation
Report A Generation
Report B Generation
Evidence of Disease
Confirmed Laboratory Result Suggestive Evidence of Disease ROUTINE NOTIFICATION
Confirmed Laboratory Result Definitive Evidence of Disease ROUTINE NOTIFICATION
Notes

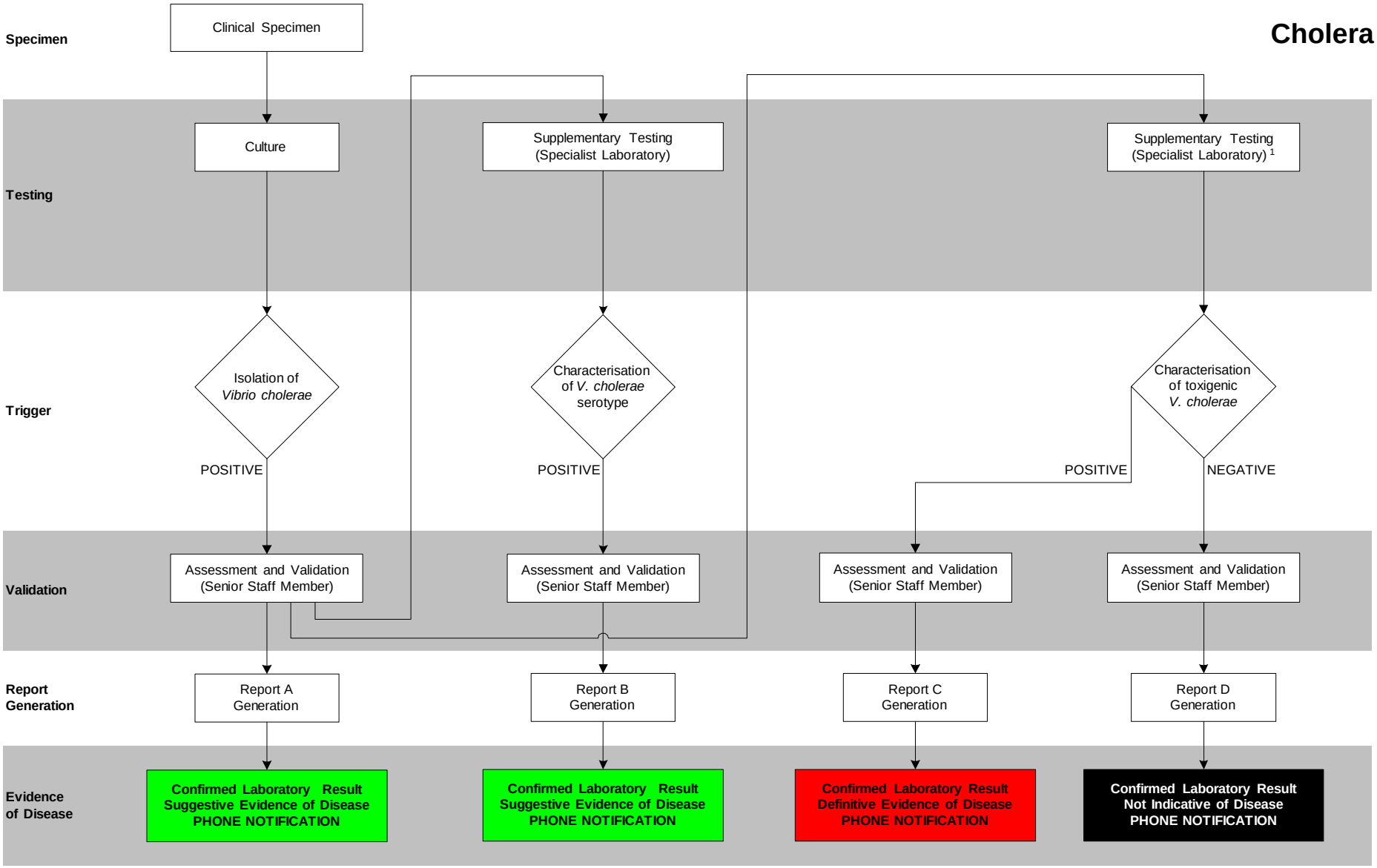
Chlamydia Trachomatis (non LGV)



Notes

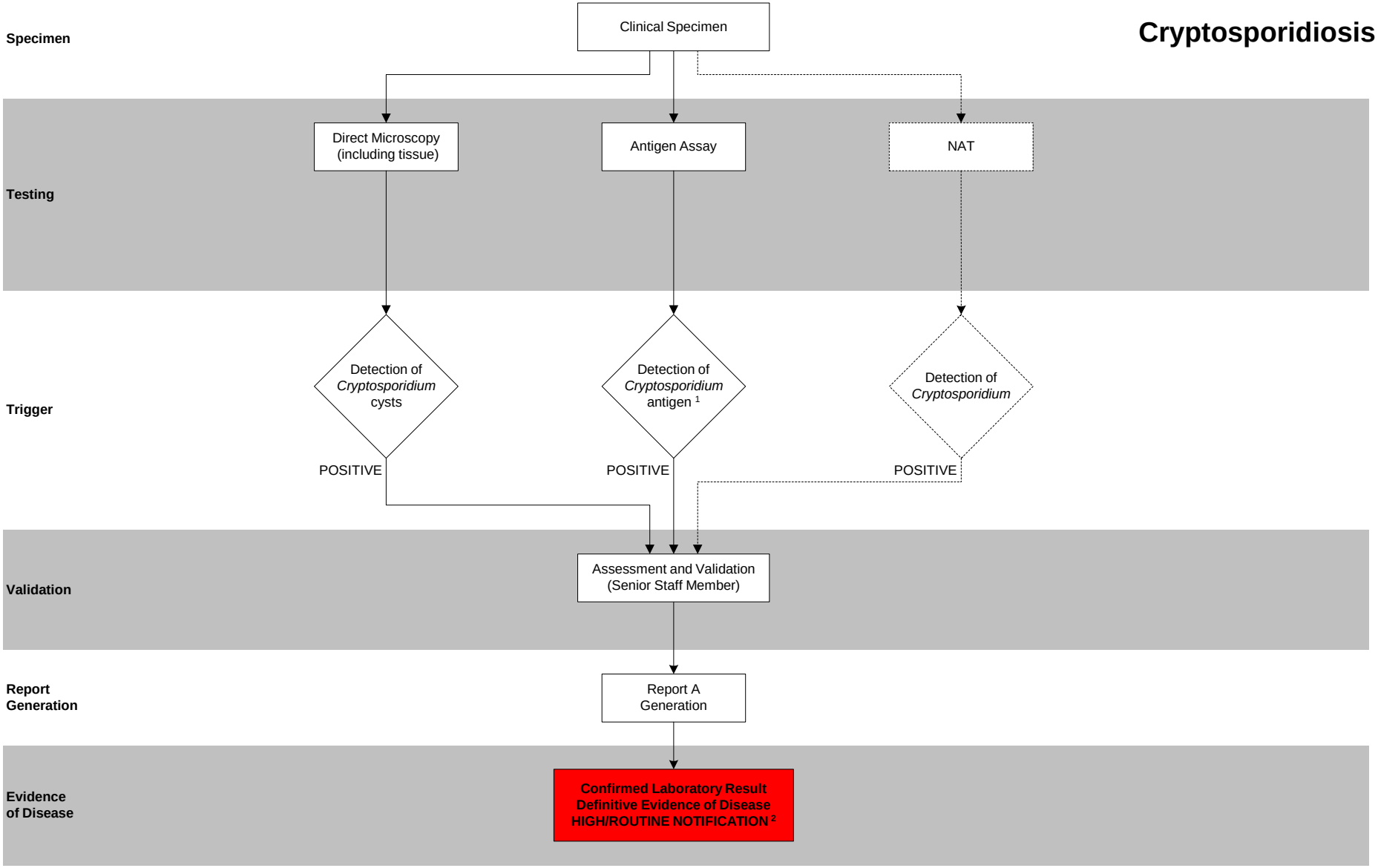
1 Antigen detection assay result should be confirmed with an appropriate test
2 Commercial assays for *C. trachomatis* have only been validated for genital/urinary specimens

Cholera



Notes 1 All *Vibrio cholerae* isolates should be referred to a specialist laboratory for further characterisation and laboratories should notify all toxigenicity testing results, whether positive or negative

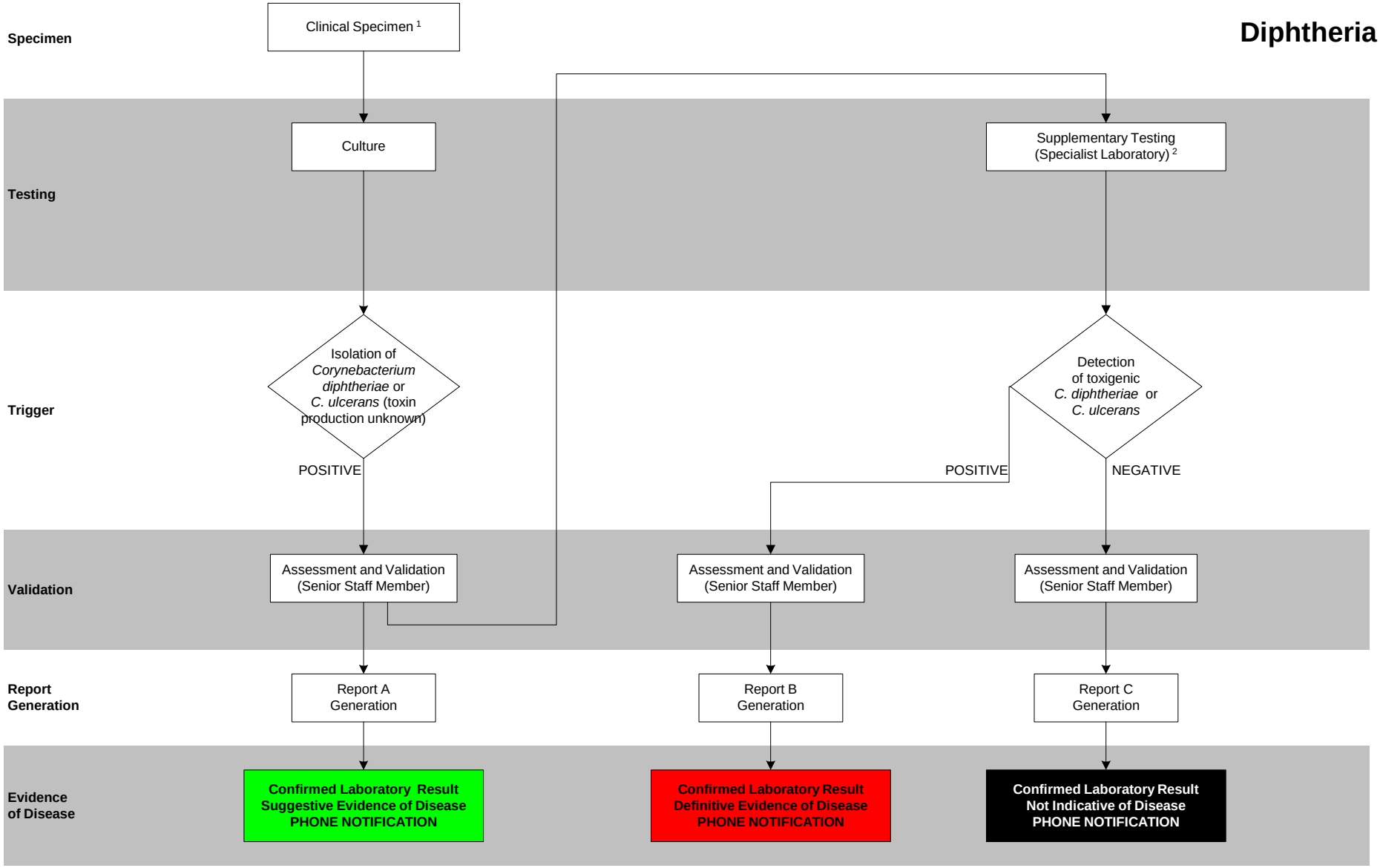
Cryptosporidiosis



Notes

1 Confirmation by microscopy recommended
2 **HIGH** public health priority if in a cluster, **ROUTINE** priority for all others

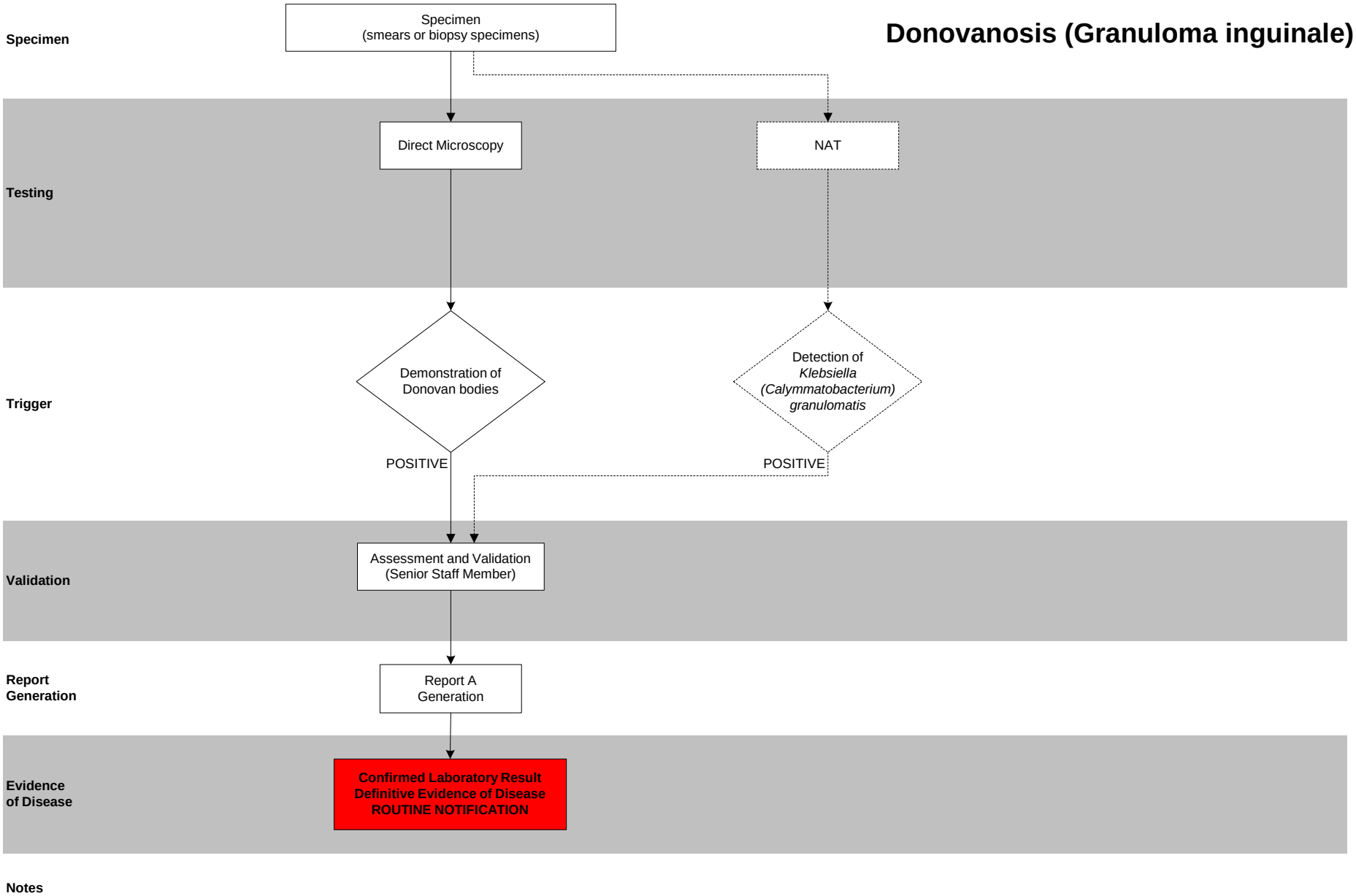
Diphtheria



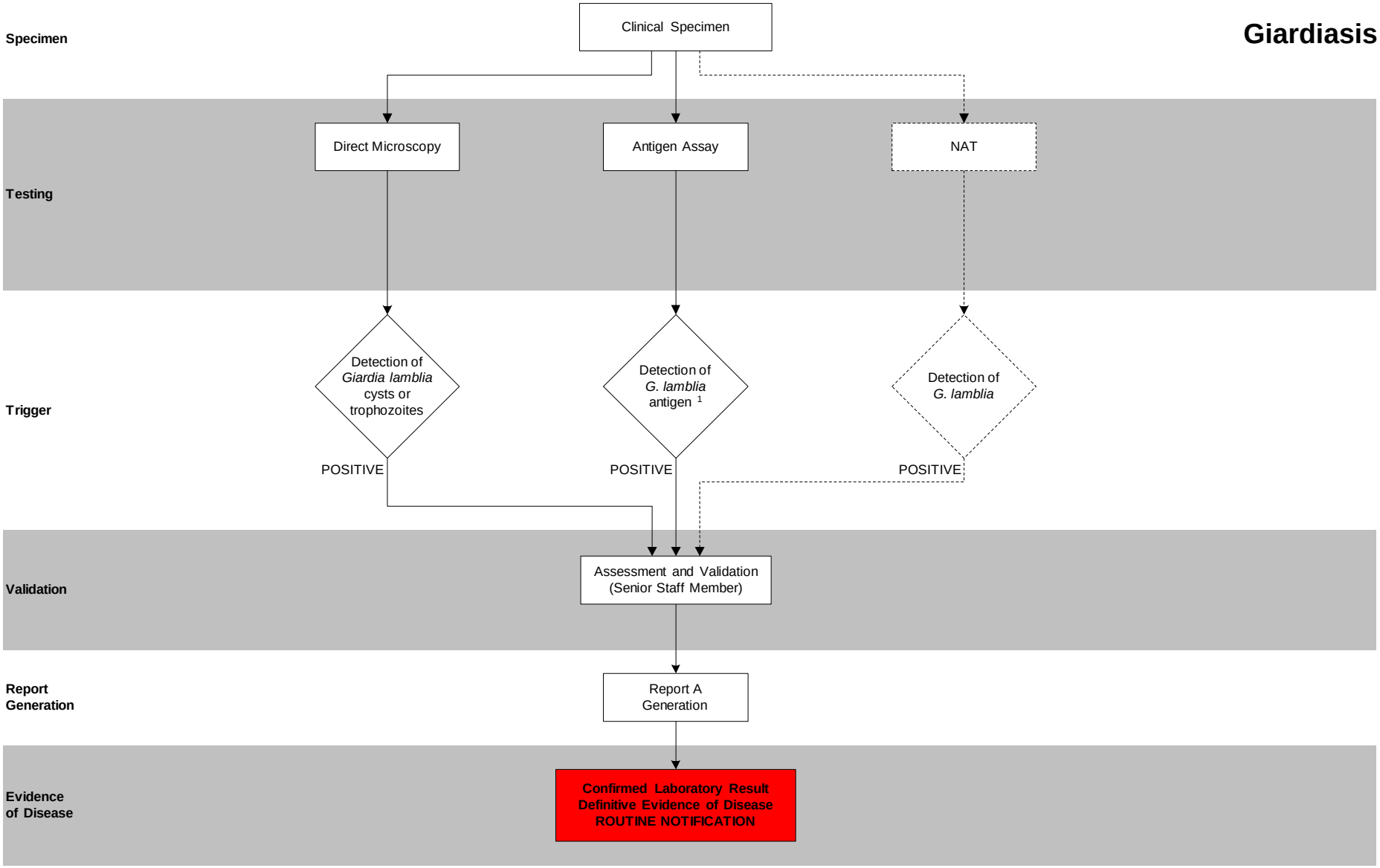
Notes

1 Isolates from non-pharyngeal diphtheria should also be notified
2 All *Corynebacterium* isolates should be referred to a specialist laboratory for further characterisation and laboratories should notify all toxigenicity testing results, whether positive or negative

Donovanosis (Granuloma inguinale)

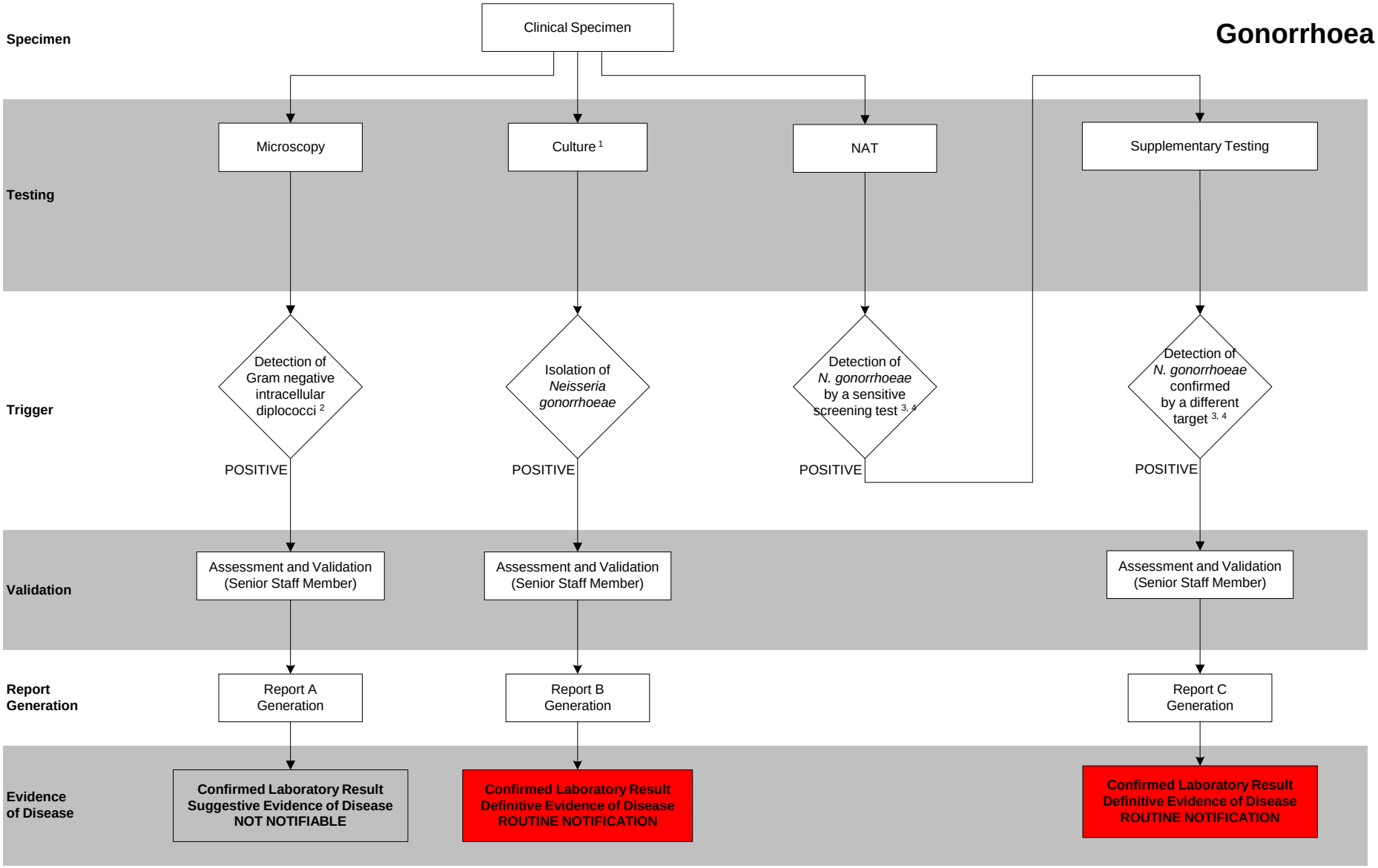


Giardiasis



Notes 1 Confirmation by microscopy recommended

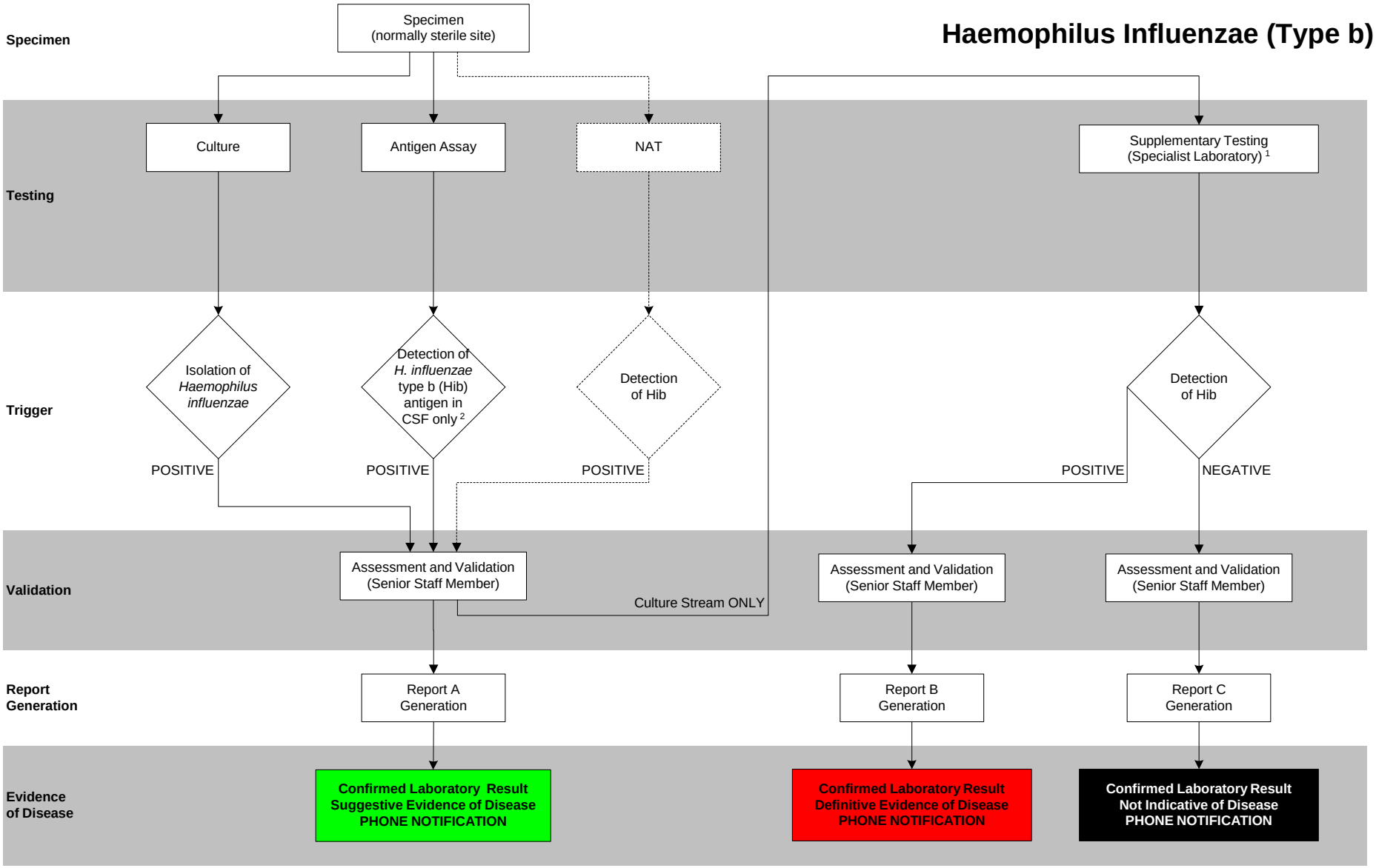
Gonorrhoea



Notes

1 It is recommended that culture be performed where possible
2 In smears of urethral exudates from symptomatic men or endocervical secretions from women
3 Commercial assays for *N. gonorrhoeae* have only been validated for genital/urinary specimens
4 Positive and negative predictive values (PPV/NPV) of PCR tests will depend on primer design and the test population (discrepant results should not be notified)

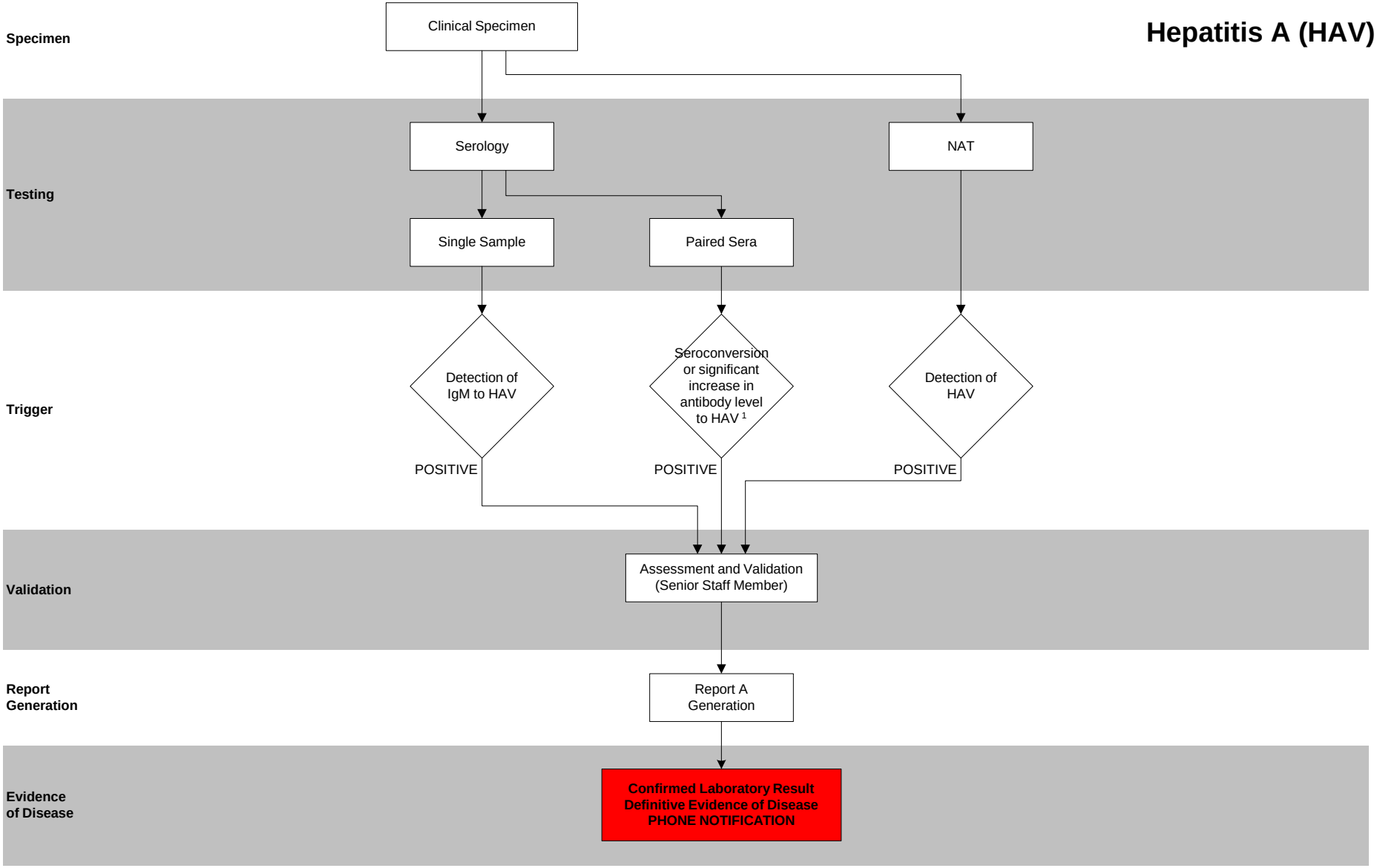
Haemophilus Influenzae (Type b)



Notes

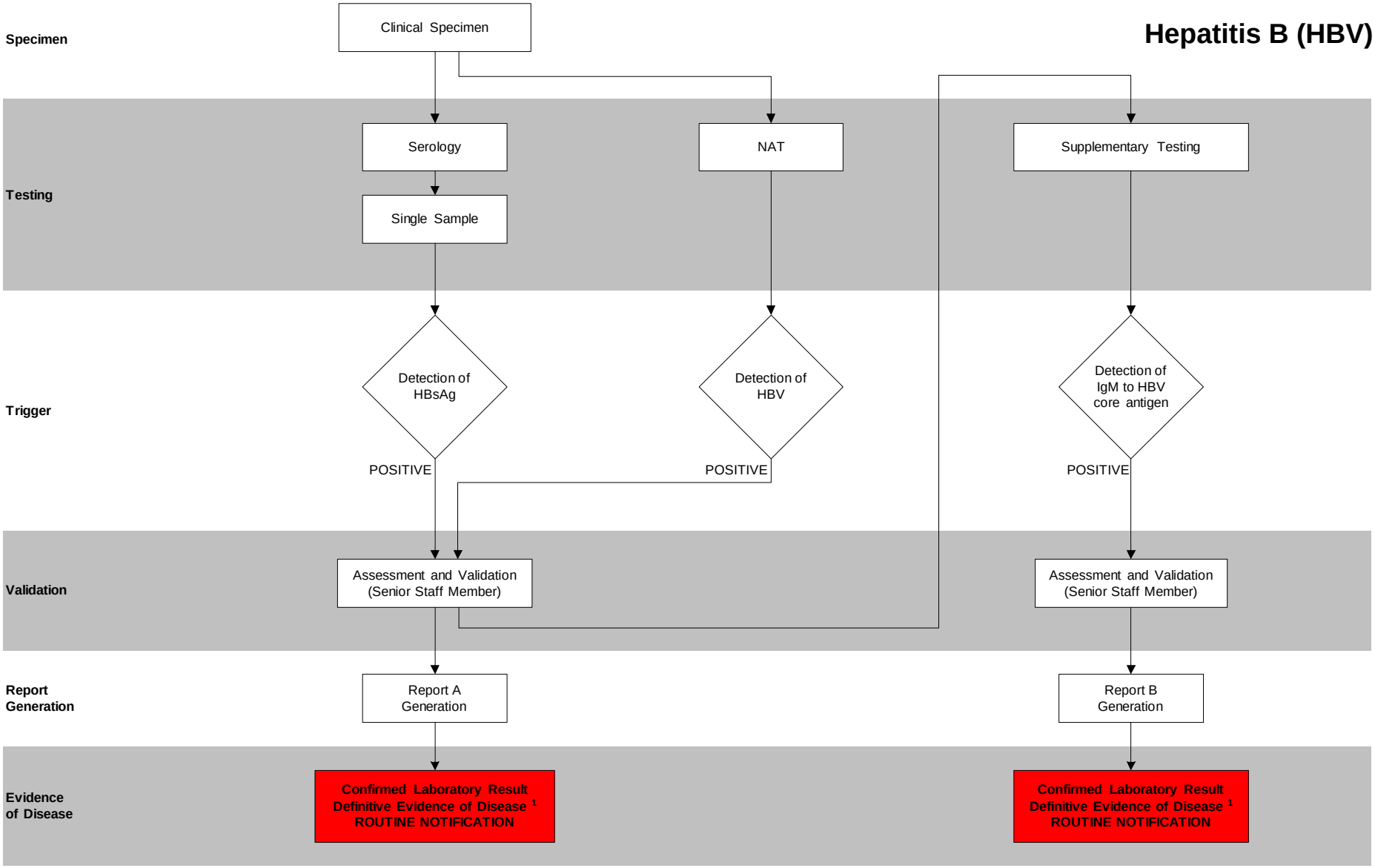
1 All *Haemophilus influenzae* isolates should be referred to a specialist laboratory for further characterisation and laboratories should notify all supplementary testing results, whether positive or negative
2 When other laboratory parameters are consistent with meningitis

Hepatitis A (HAV)



Notes 1 Seroconversion or significant increase in antibody level to HAV between acute and convalescent phase sera (tested in parallel at the same laboratory)

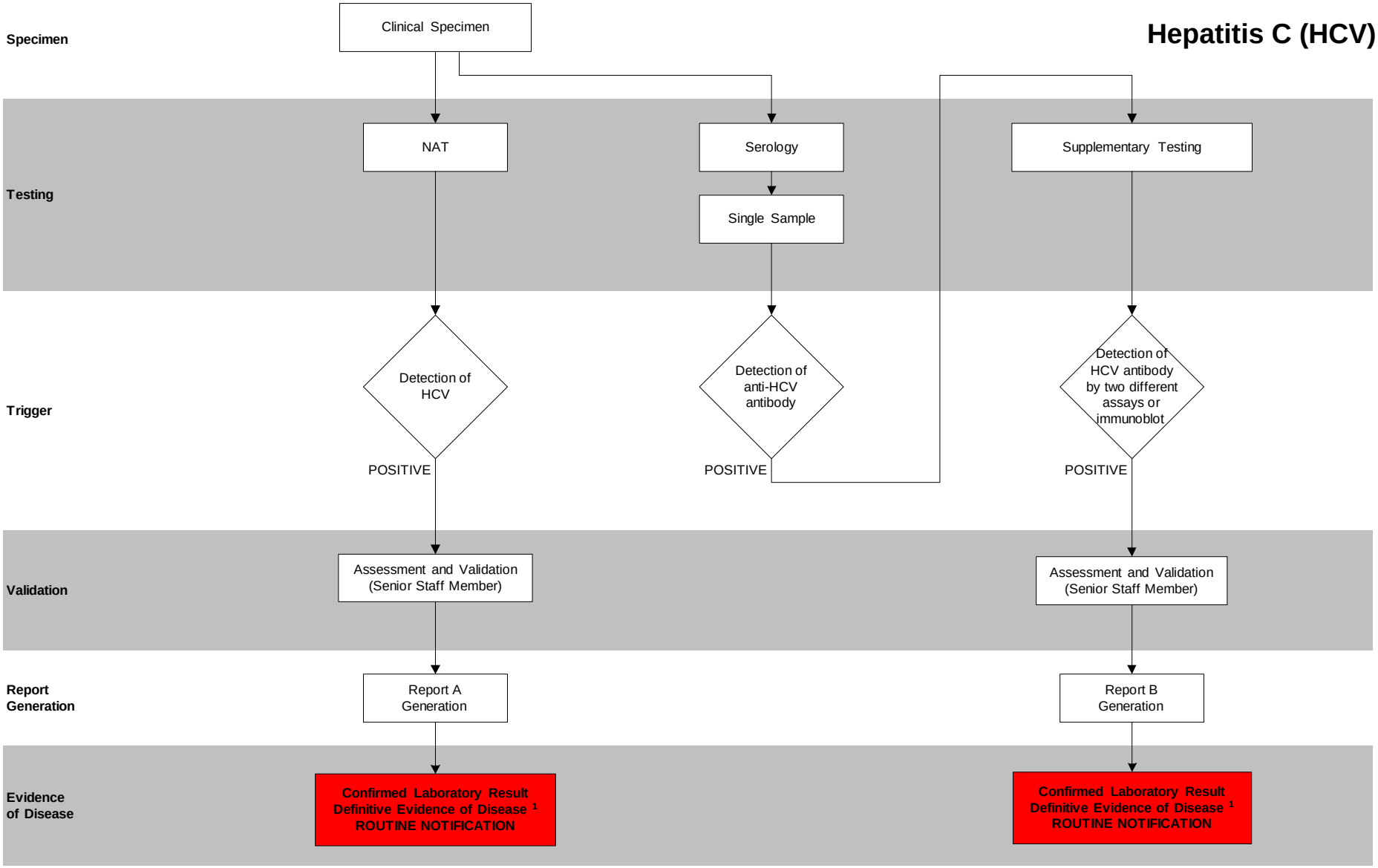
Hepatitis B (HBV)



Notes

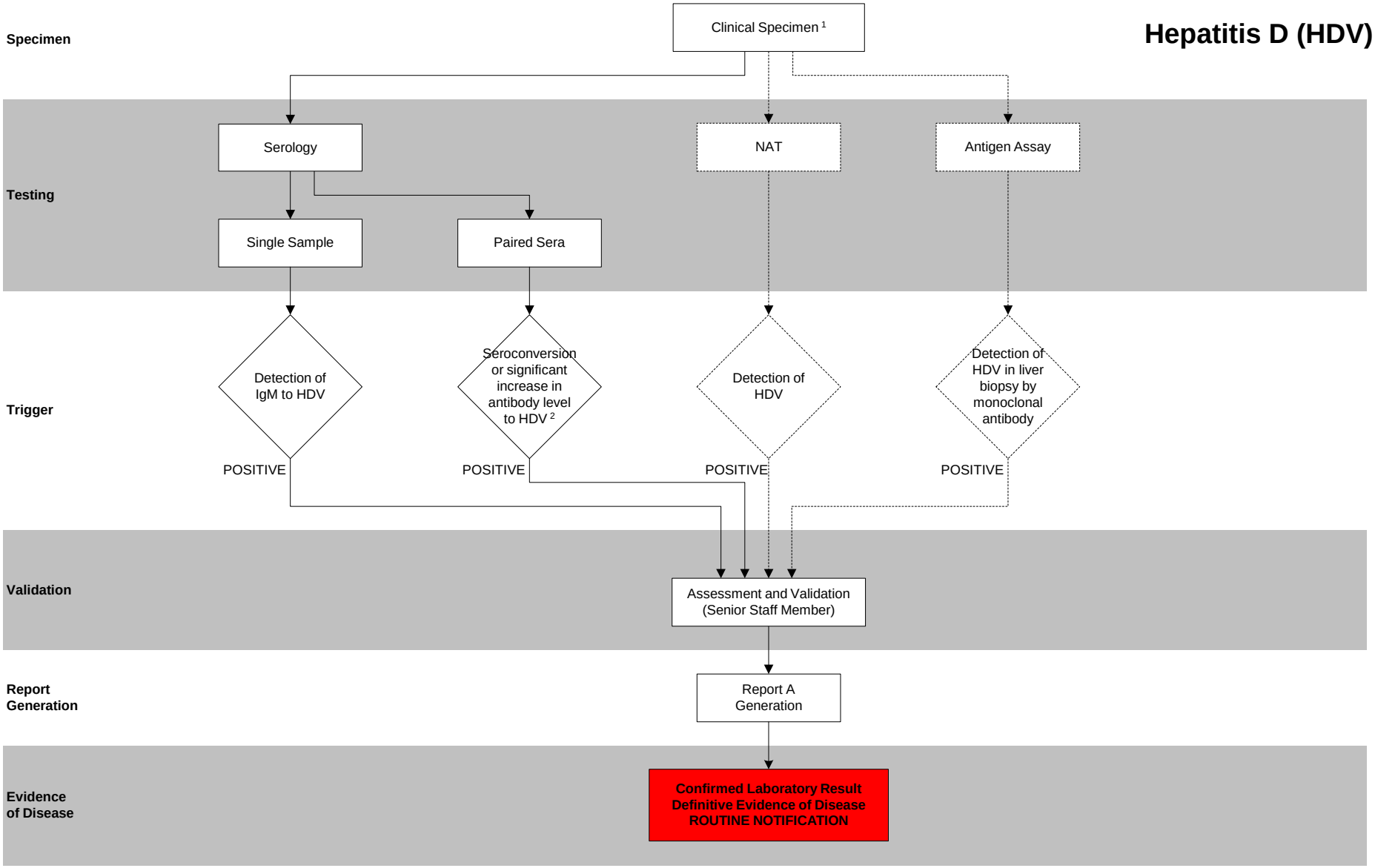
1 The patient's previous notification history and any supplementary testing (such as IgM or IgG against hepatitis B core antigen) will be considered by the public health network before further classification into acute, chronic or unspecified infection

Hepatitis C (HCV)



Notes 1 The patient's previous notification history and any supplementary testing will be considered by the public health network before further classification into acute, chronic, past or unspecified infection

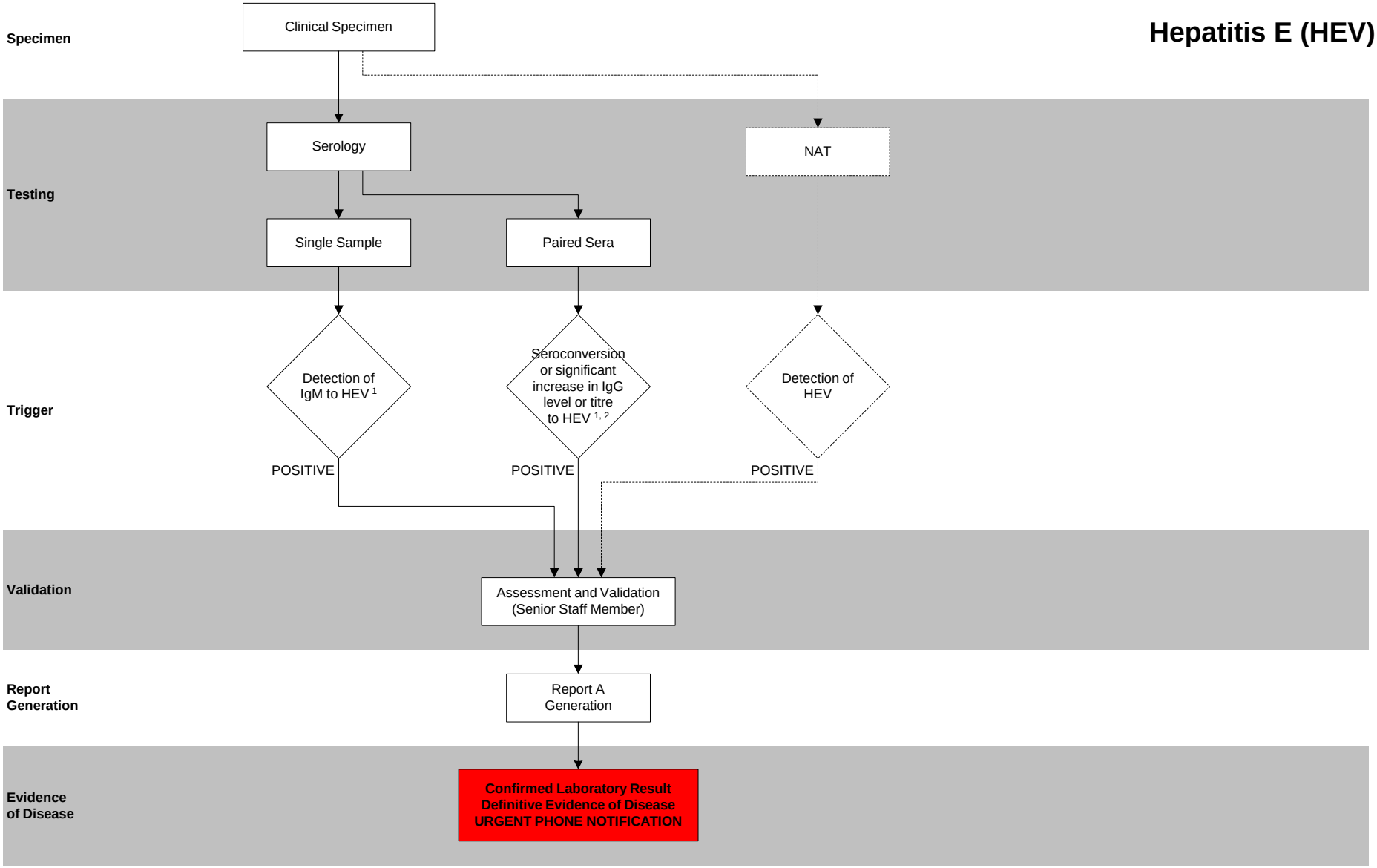
Hepatitis D (HDV)



Notes

1 Tested only on patients infected with hepatitis B virus
2 Seroconversion or significant increase in antibody level to HDV between acute and convalescent phase sera (tested in parallel at the same laboratory)

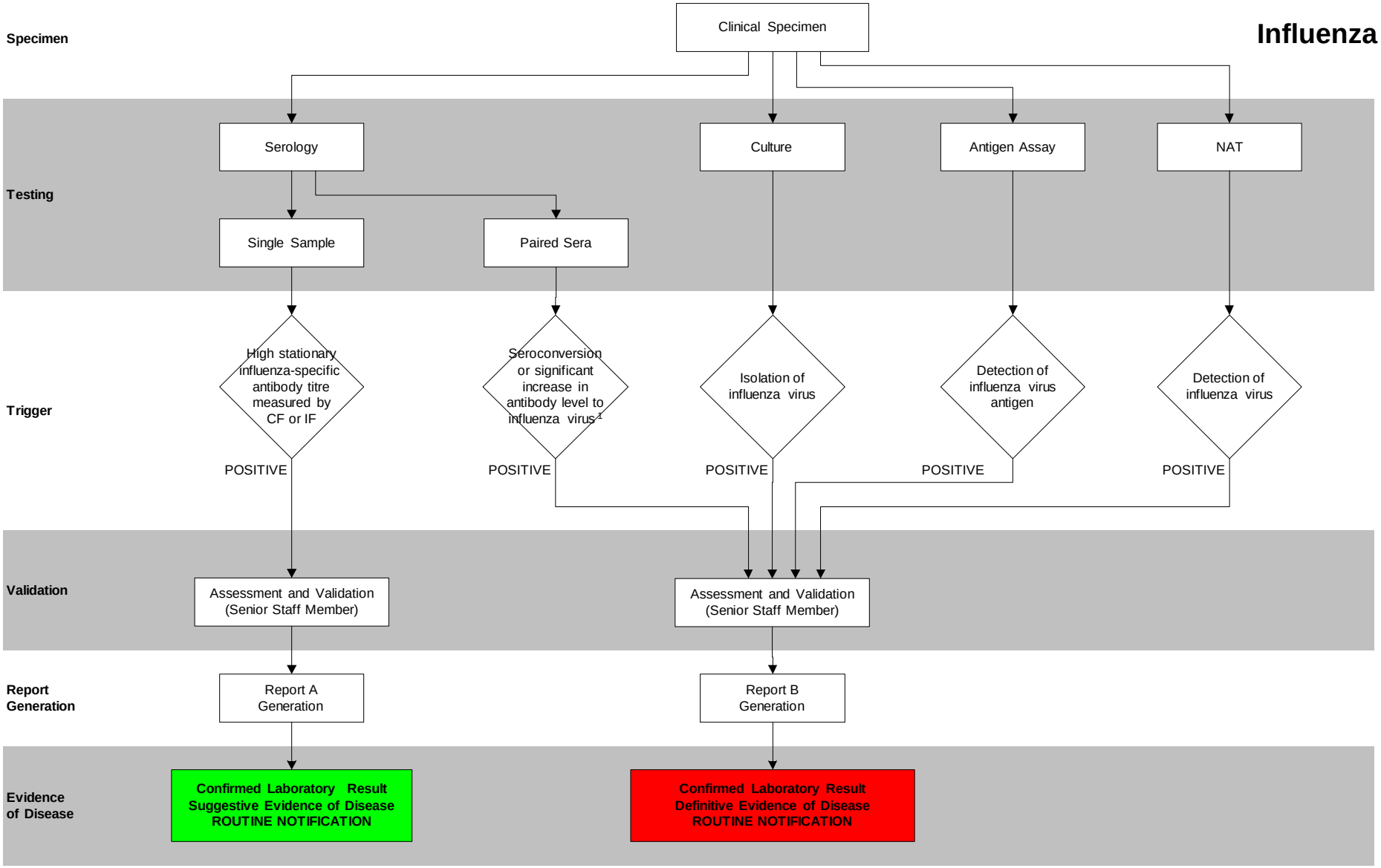
Hepatitis E (HEV)



Notes

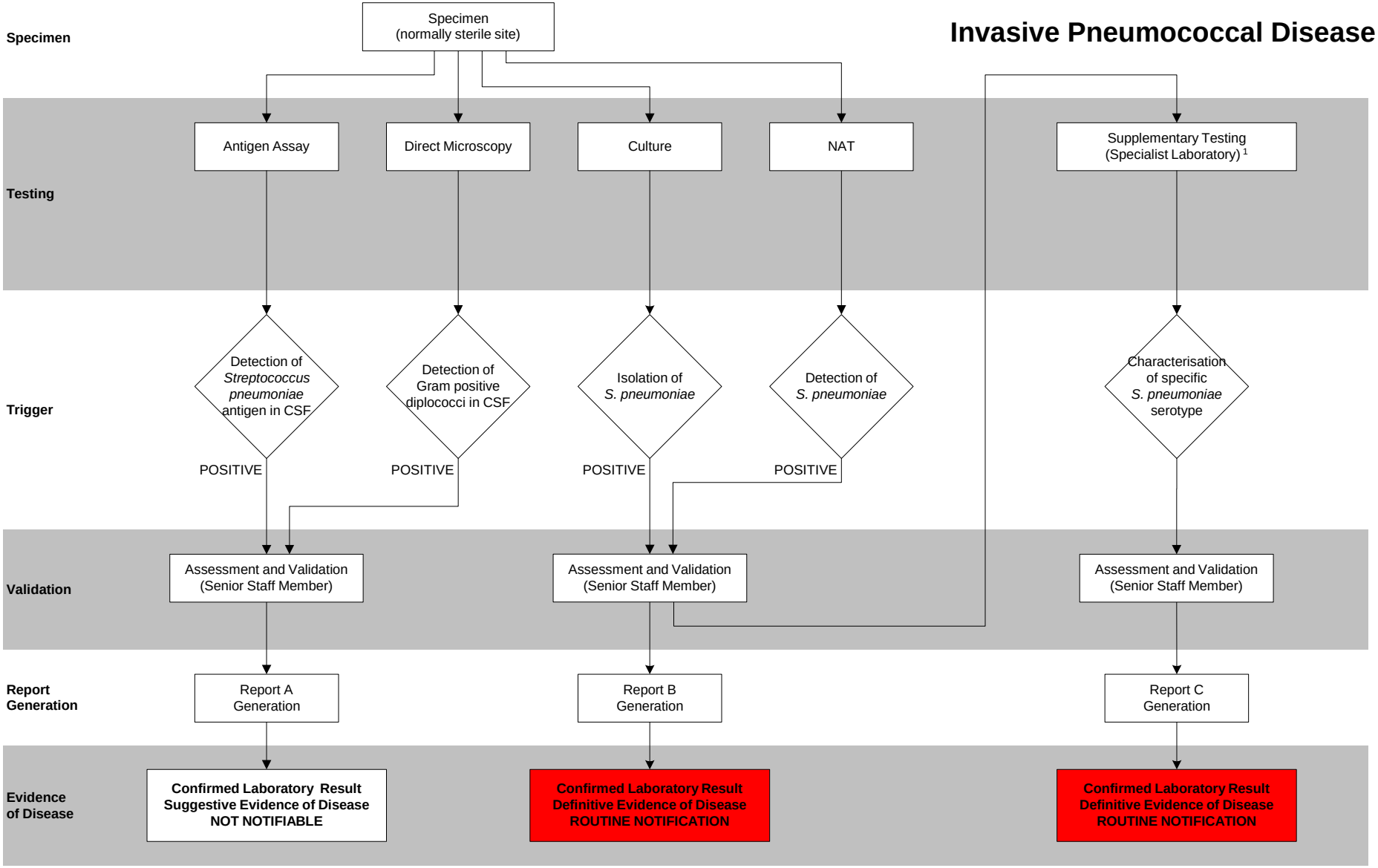
1 If the person has not travelled outside Australia in the preceding 3 months, the antibody result must be confirmed by a specialist laboratory
2 Seroconversion or significant increase in IgG level or titre to HEV between acute and convalescent phase sera (tested in parallel at the same laboratory)

Influenza



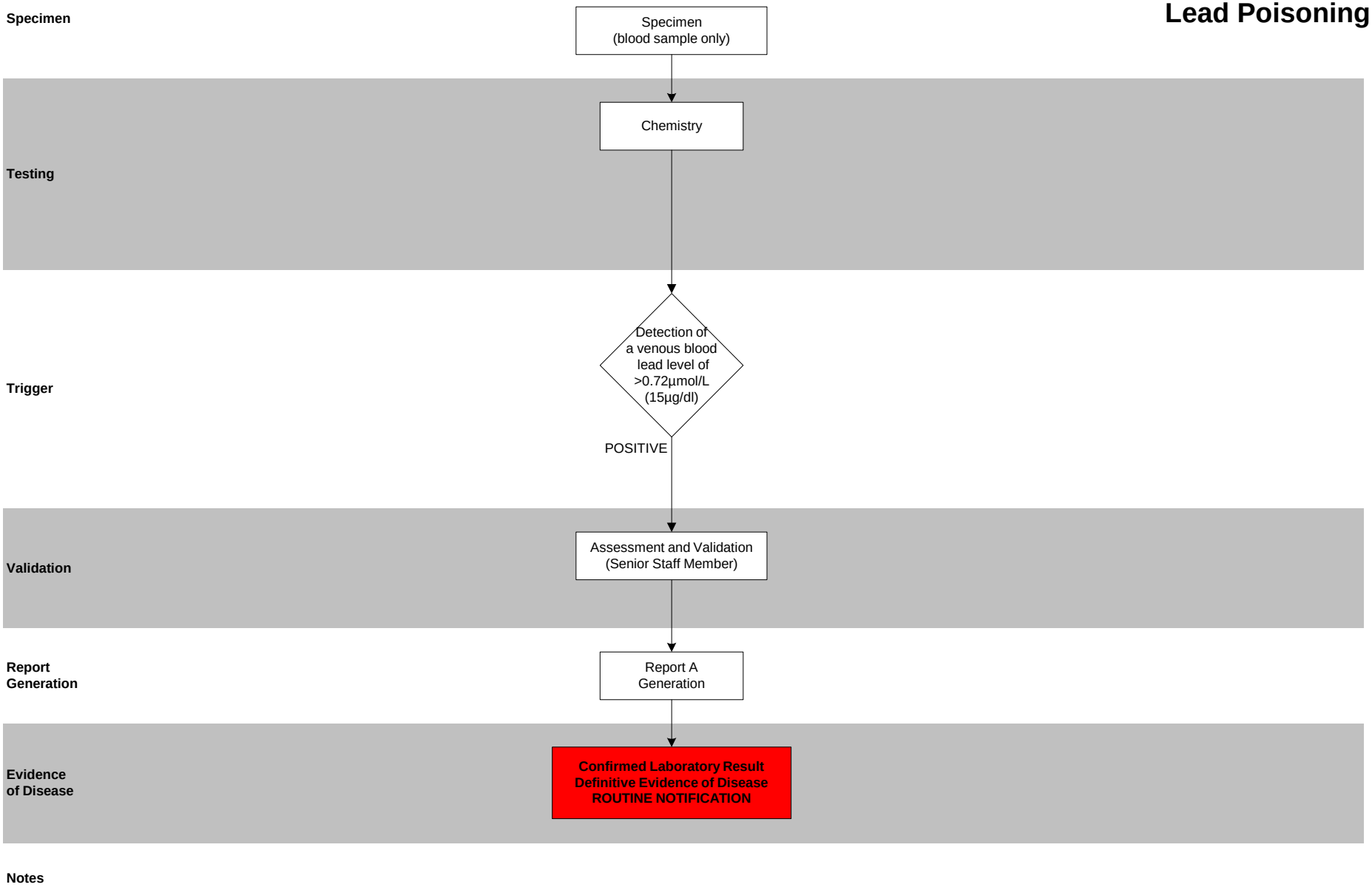
Notes 1 Seroconversion or significant increase in antibody level to influenza virus between acute and convalescent phase sera (tested in parallel at the same laboratory)

Invasive Pneumococcal Disease

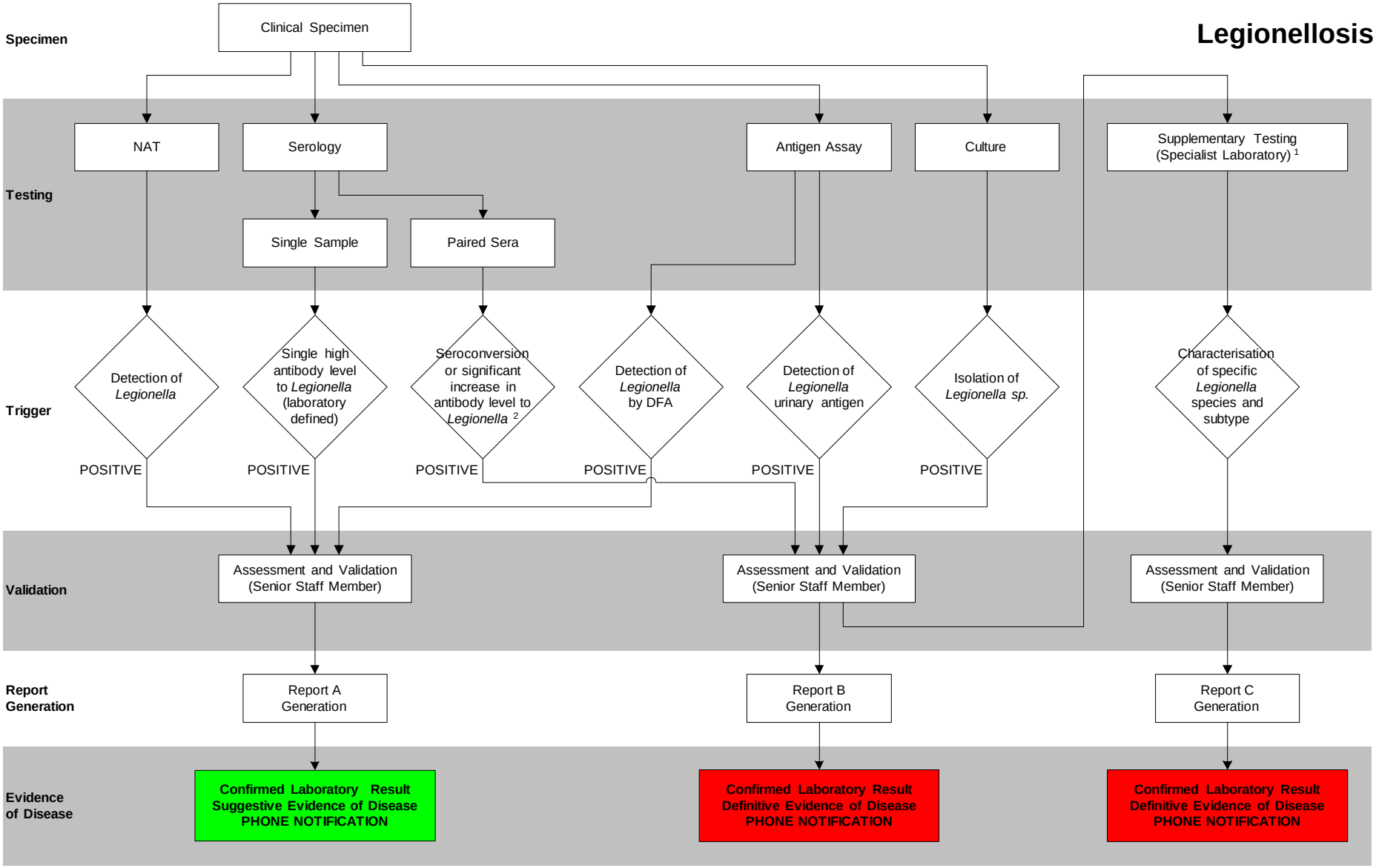


Notes 1 All *Streptococcus pneumoniae* isolates should be referred to a specialist laboratory for further characterisation

Lead Poisoning

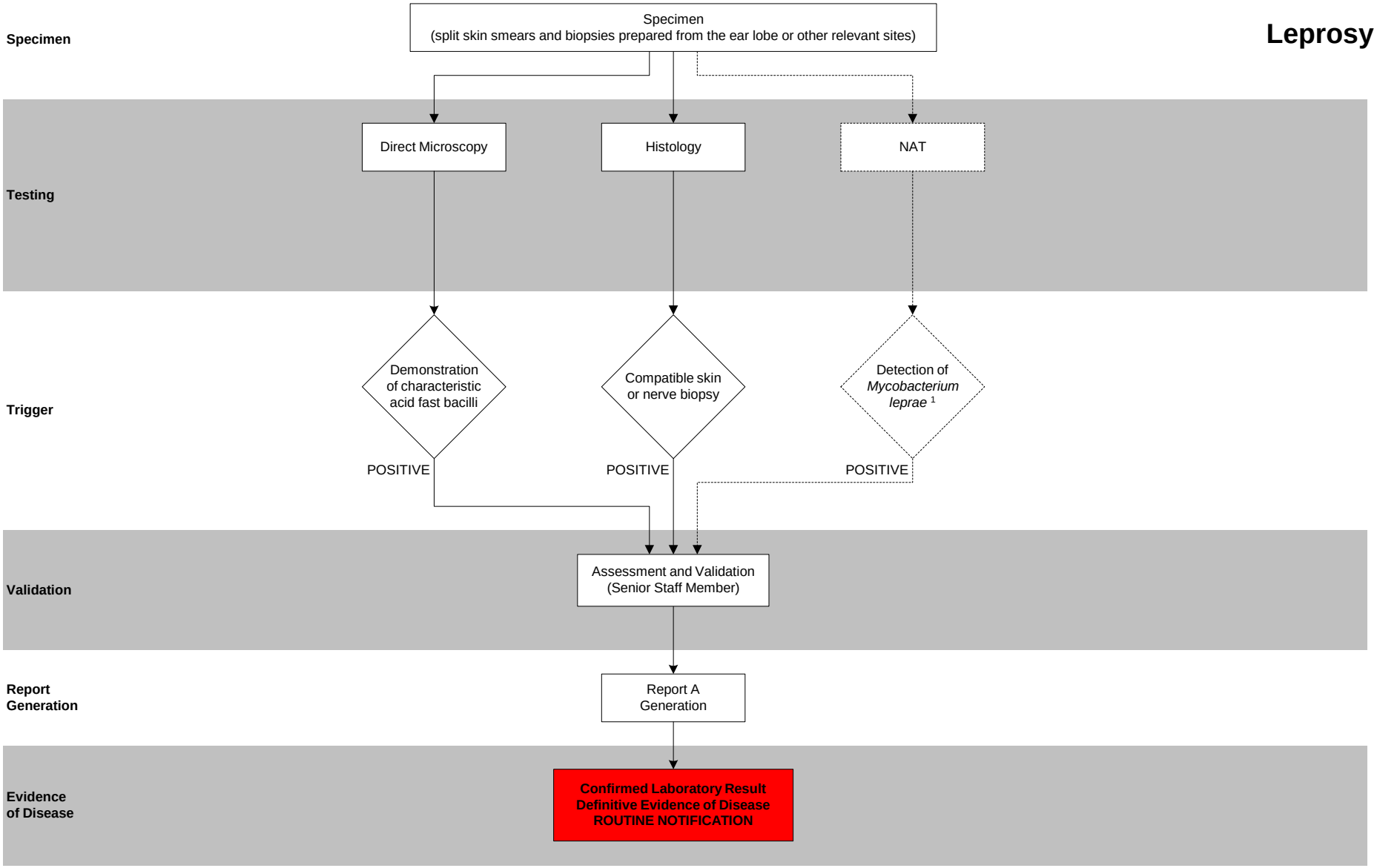


Legionellosis



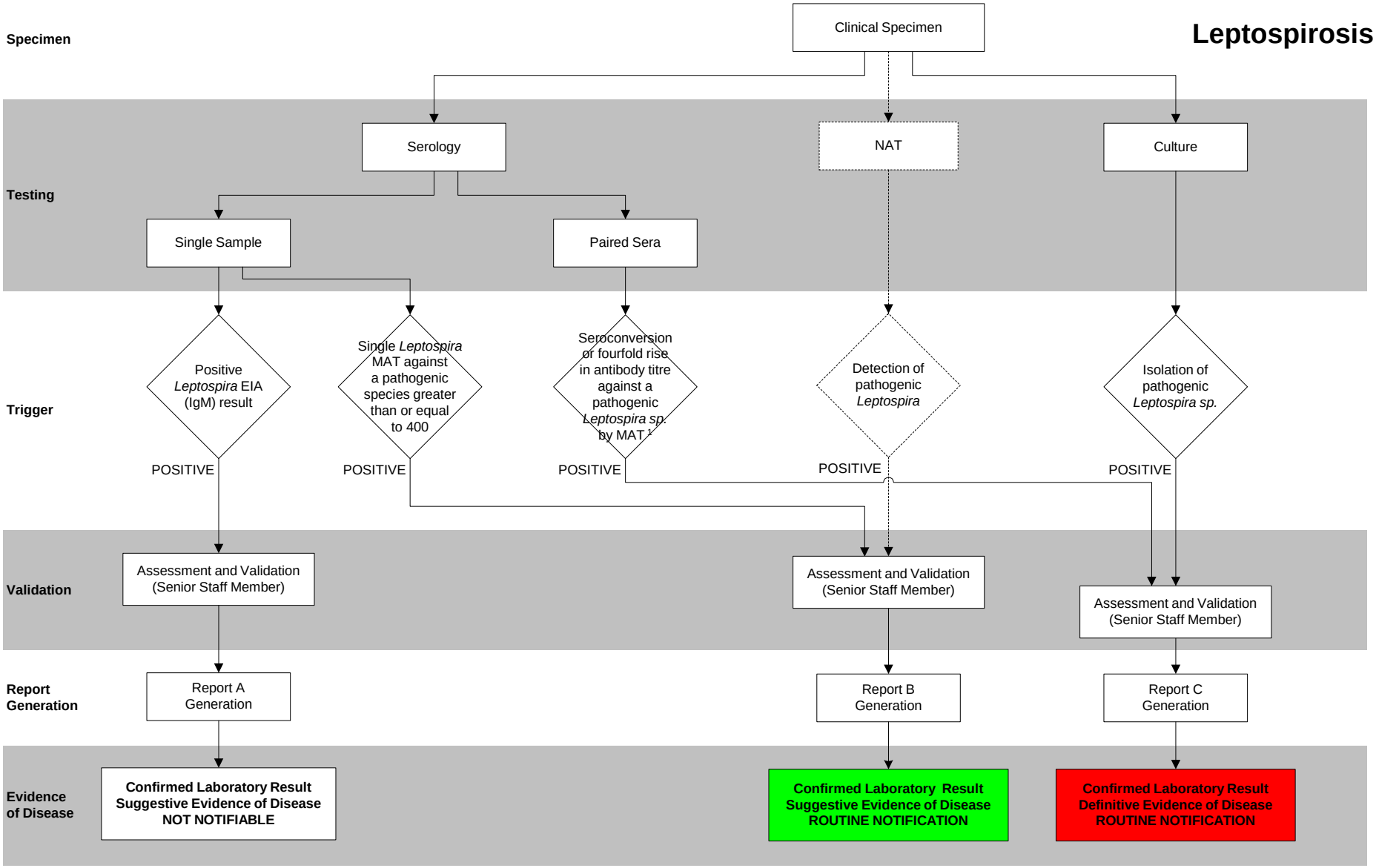
Notes
1 All *Legionella* isolates should be referred to a specialist laboratory for further characterisation
2 Seroconversion or significant increase in antibody level to *Legionella* between acute and convalescent phase sera (tested in parallel at the same laboratory)

Leprosy



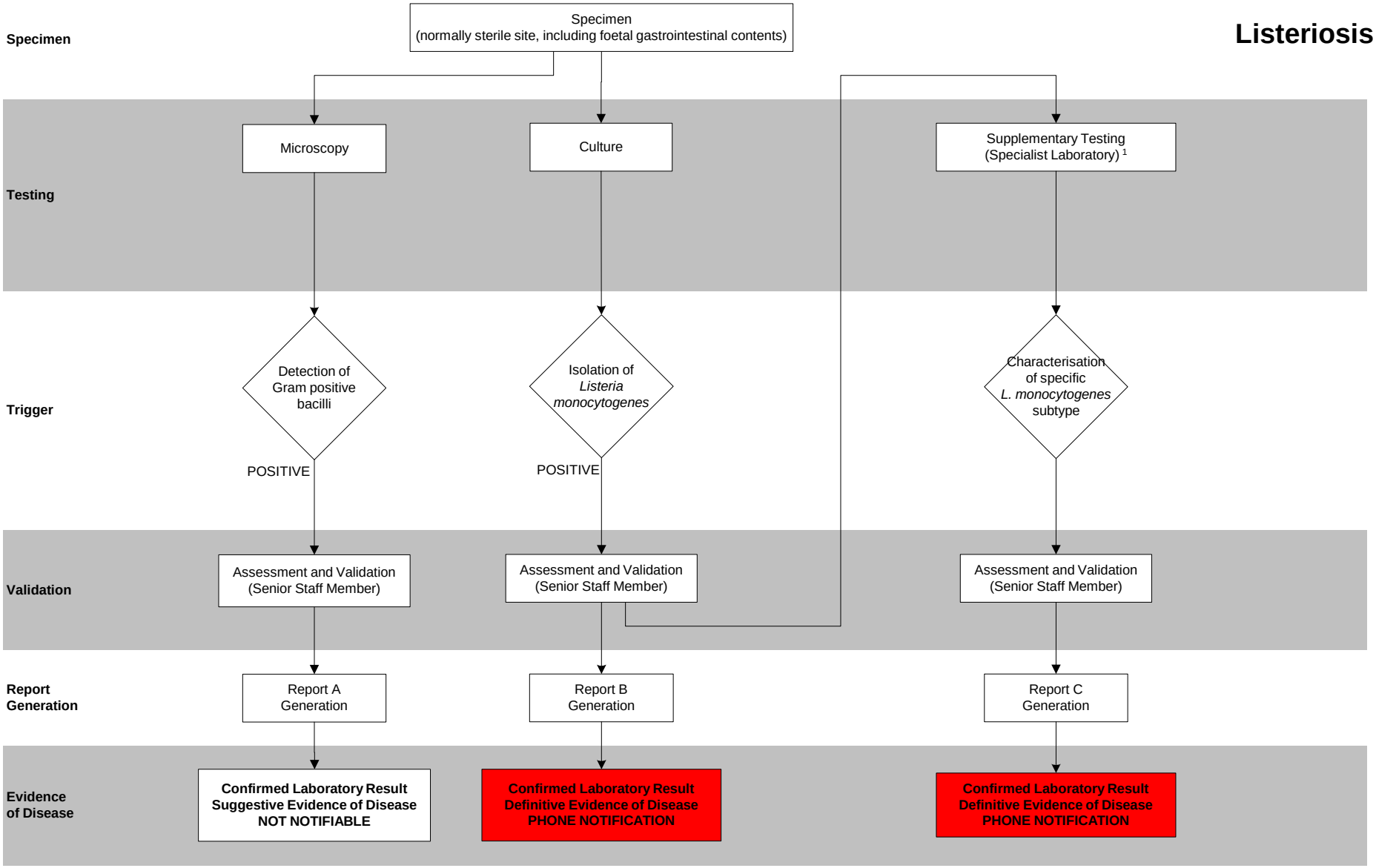
Notes 1 Where confirmed by sequencing or validated species-specific PCR

Leptospirosis



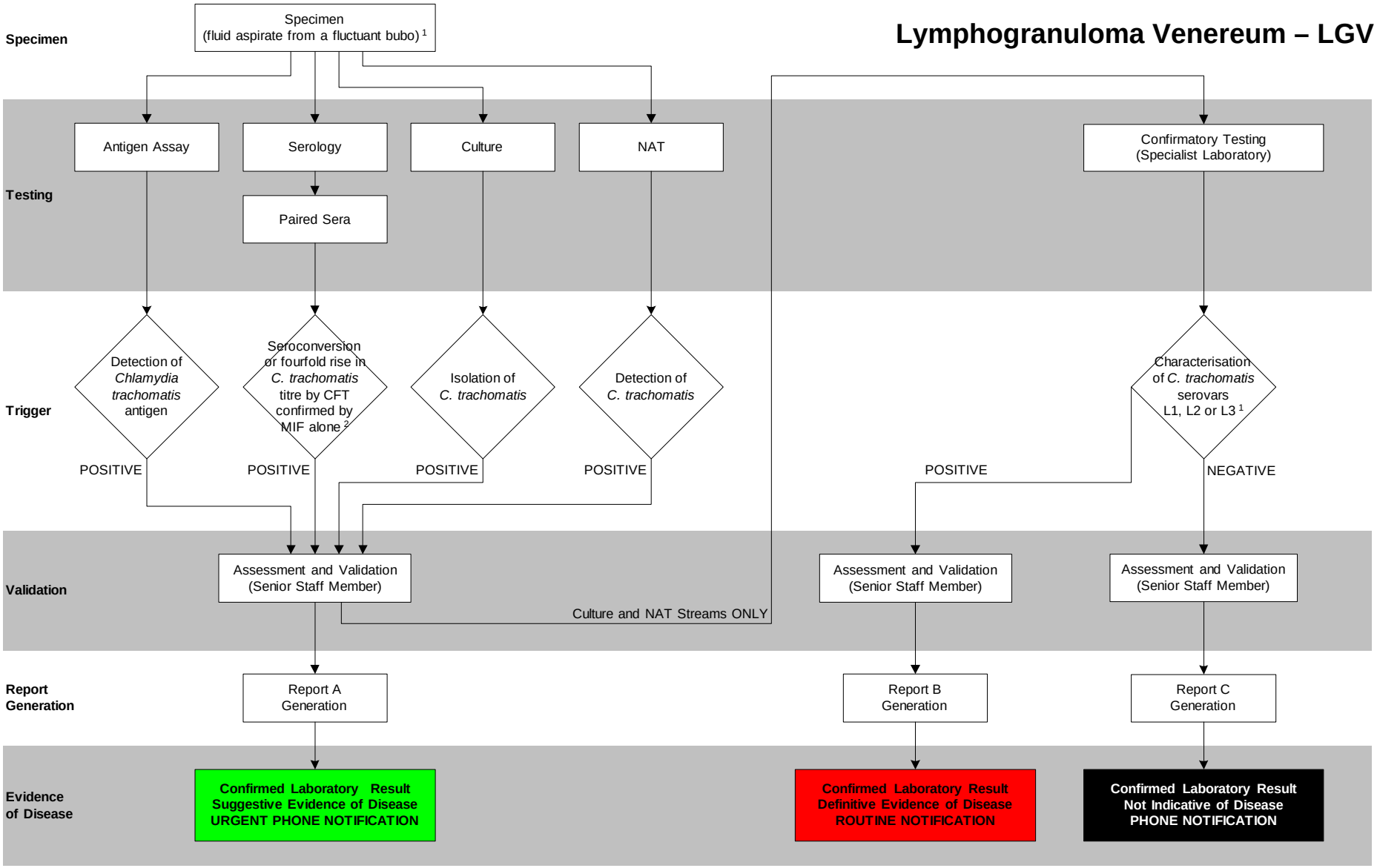
Notes 1 A fourfold or greater rise in *Leptospira* agglutination titre between acute and convalescent phase sera (tested in parallel at the same laboratory)

Listeriosis



Notes 1 All *Listeria monocytogenes* isolates should be referred to a specialist laboratory for fur further characterisation

Lymphogranuloma Venereum – LGV

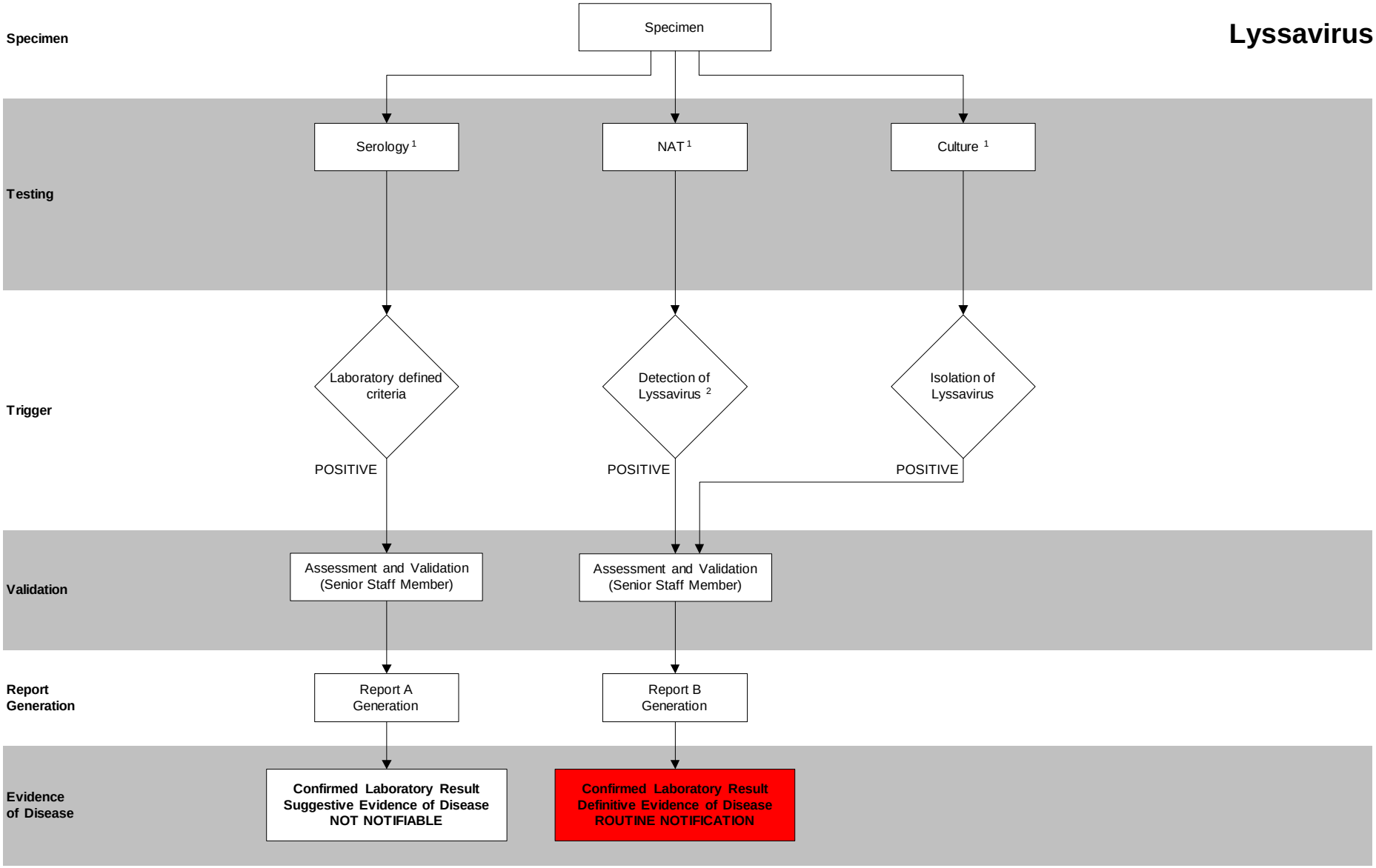


Notes

1 Characterisation of C. trachomatis serovars L1, L2 and L3 in genital or rectal specimens also constitutes definitive evidence of disease

2 Seroconversion or fourfold rise in *Chlamydia trachomatis* titre by CFT, confirmed by MIF alone, between acute and convalescent phase sera (tested in parallel at the same laboratory)

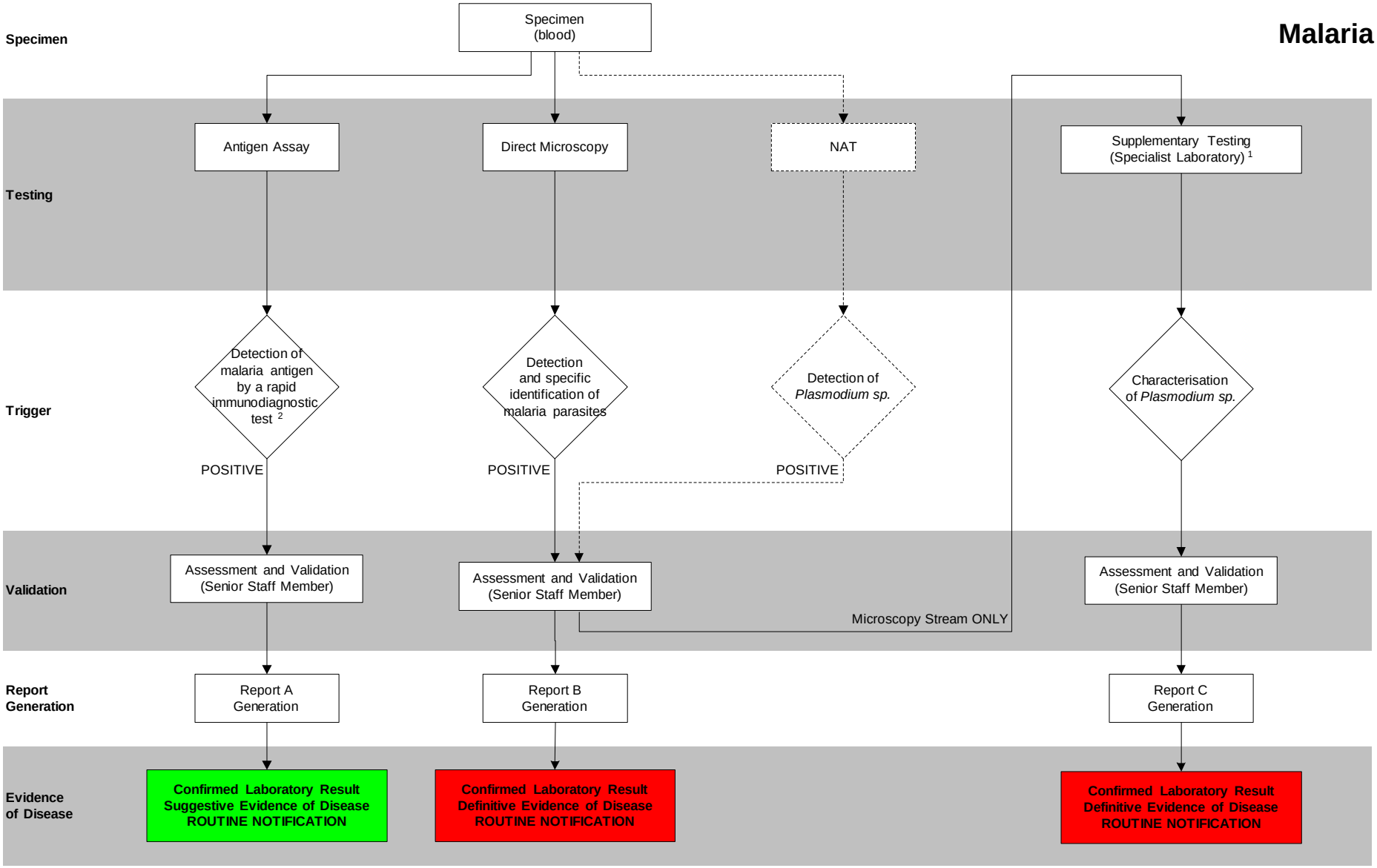
Lyssavirus



Notes

1 Testing perfomed at a specialist laboratory
2 Product amplified from CSF, nuchal biopsy, brain, salivary gland, saliva, tissue culture supernatant or equivalent formalin fixed tissue

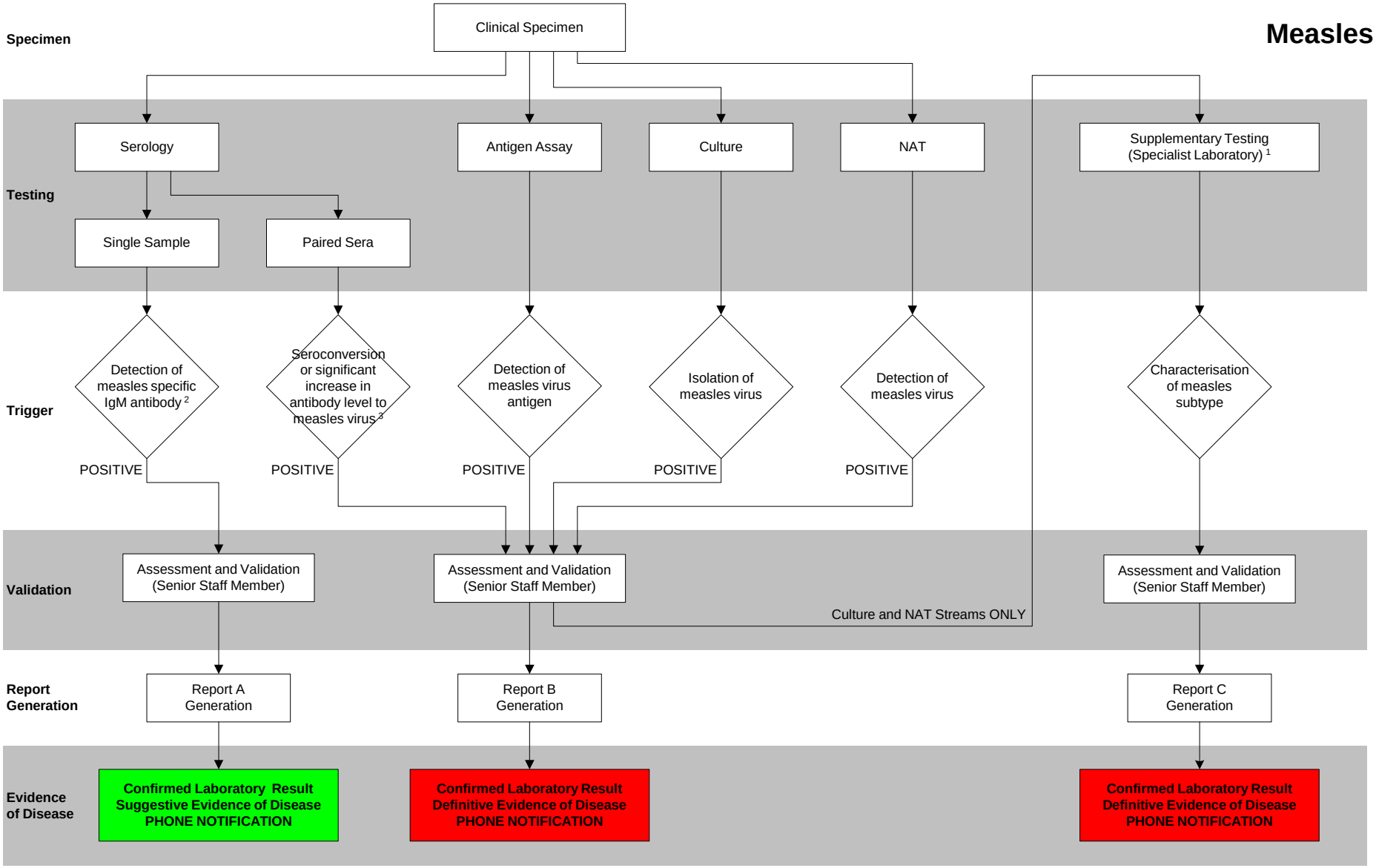
Malaria



Notes

1 Review of microscopy results by a specialist laboratory is recommended as laboratories that lack regular experience may fail to identify mixed infections and or speciate reliably
2 Rapid immunodiagnostic test should always be confirmed by microscopy

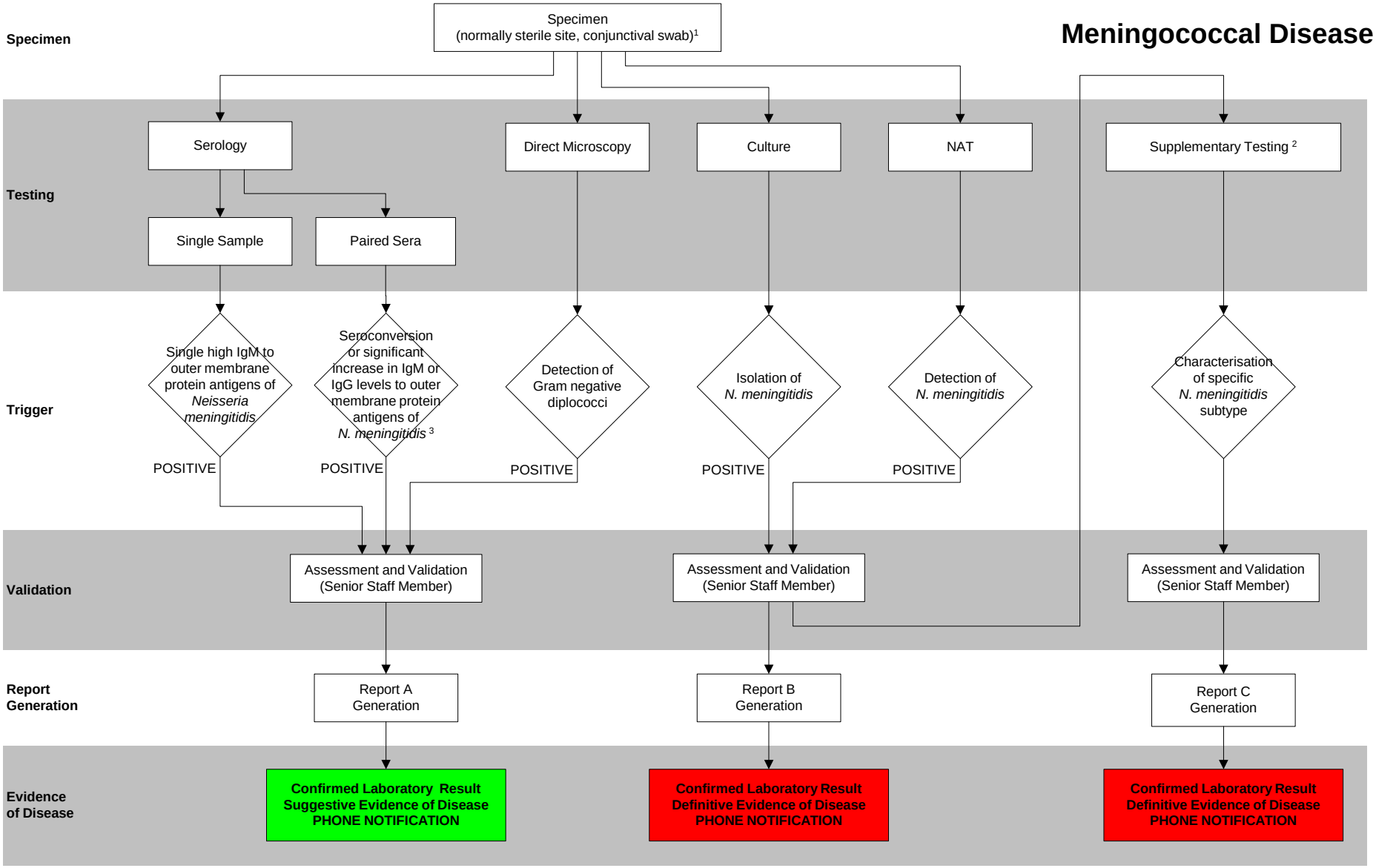
Measles



Notes

1 All measles isolates and amplification products should be referred to a specialist laboratory for further characterisation
2 It is recommended that single positive IgM results be confirmed by an alternative kit or method
3 Seroconversion or significant increase in antibody level to measles virus between acute and convalescent phase sera (tested in parallel at the same laboratory)

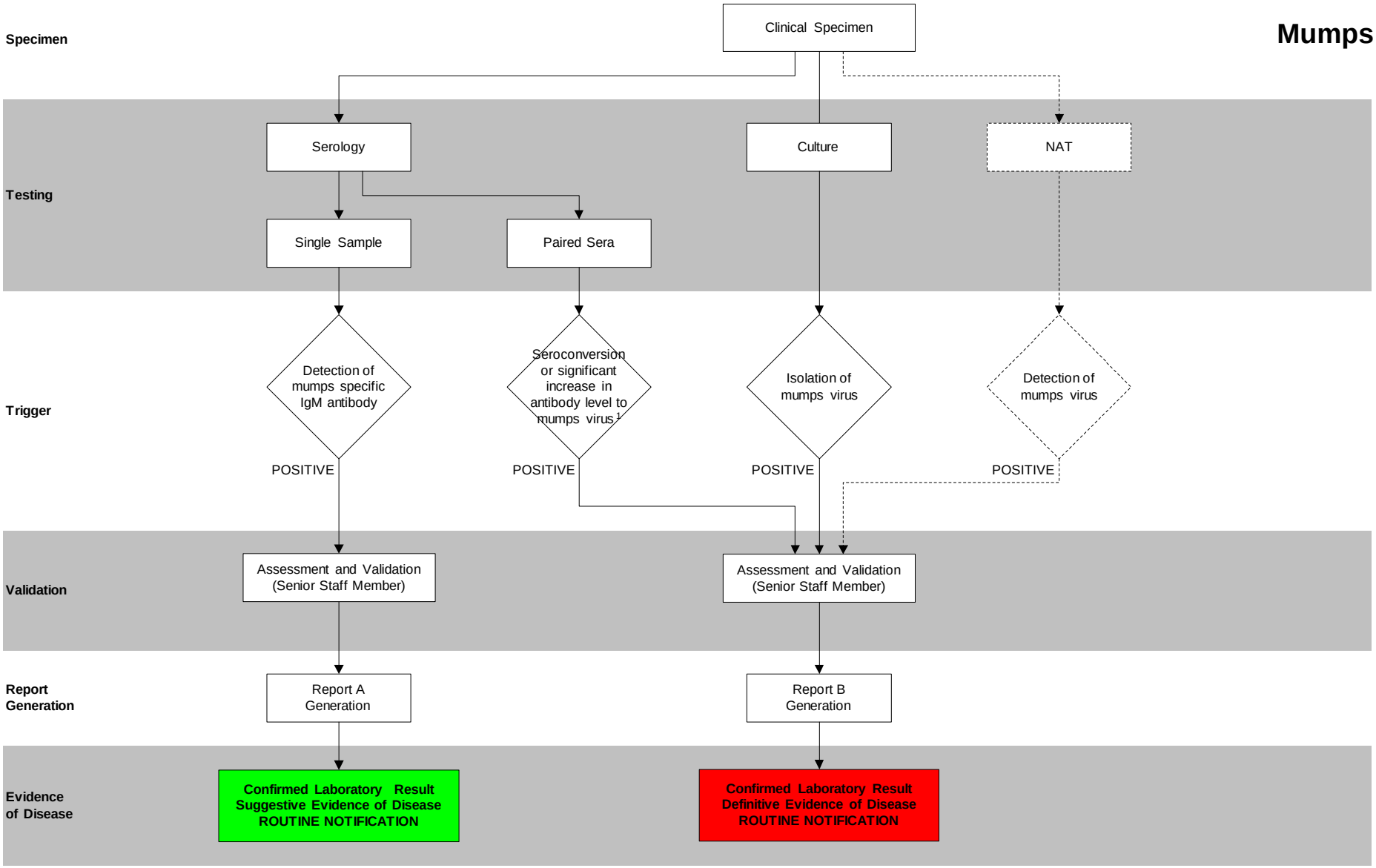
Meningococcal Disease



Notes

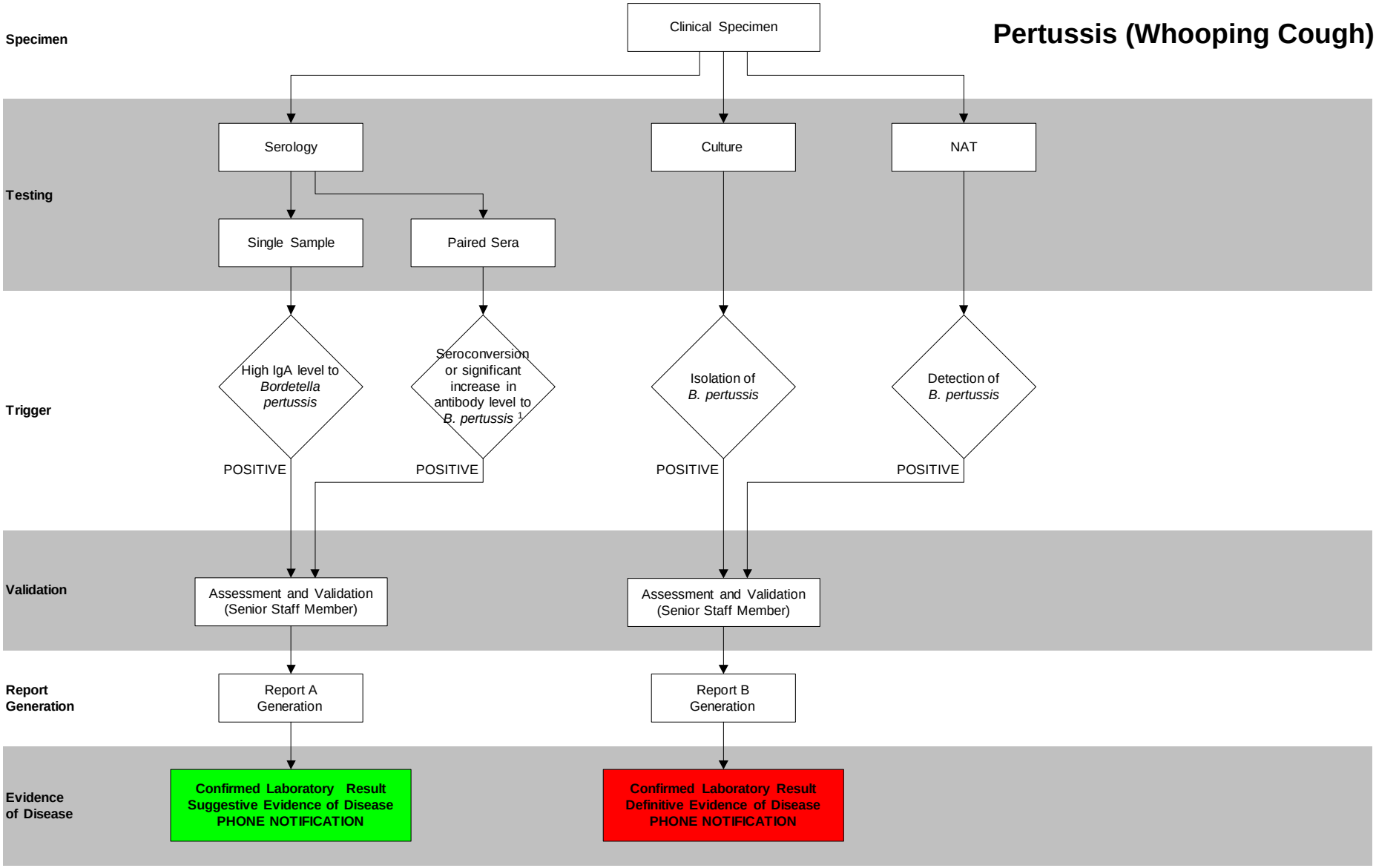
1 Notification of conjunctival isolates is required in NSW
2 All *Neisseria meningitidis* isolates and positive amplification products should be referred to a specialist laboratory for further characterisation
3 Seroconversion or significant increase in IgM or IgG levels to outer membrane protein antigen of *Neisseria meningitidis* between acute and convalescent phase sera (tested in parallel at the same laboratory)

Mumps



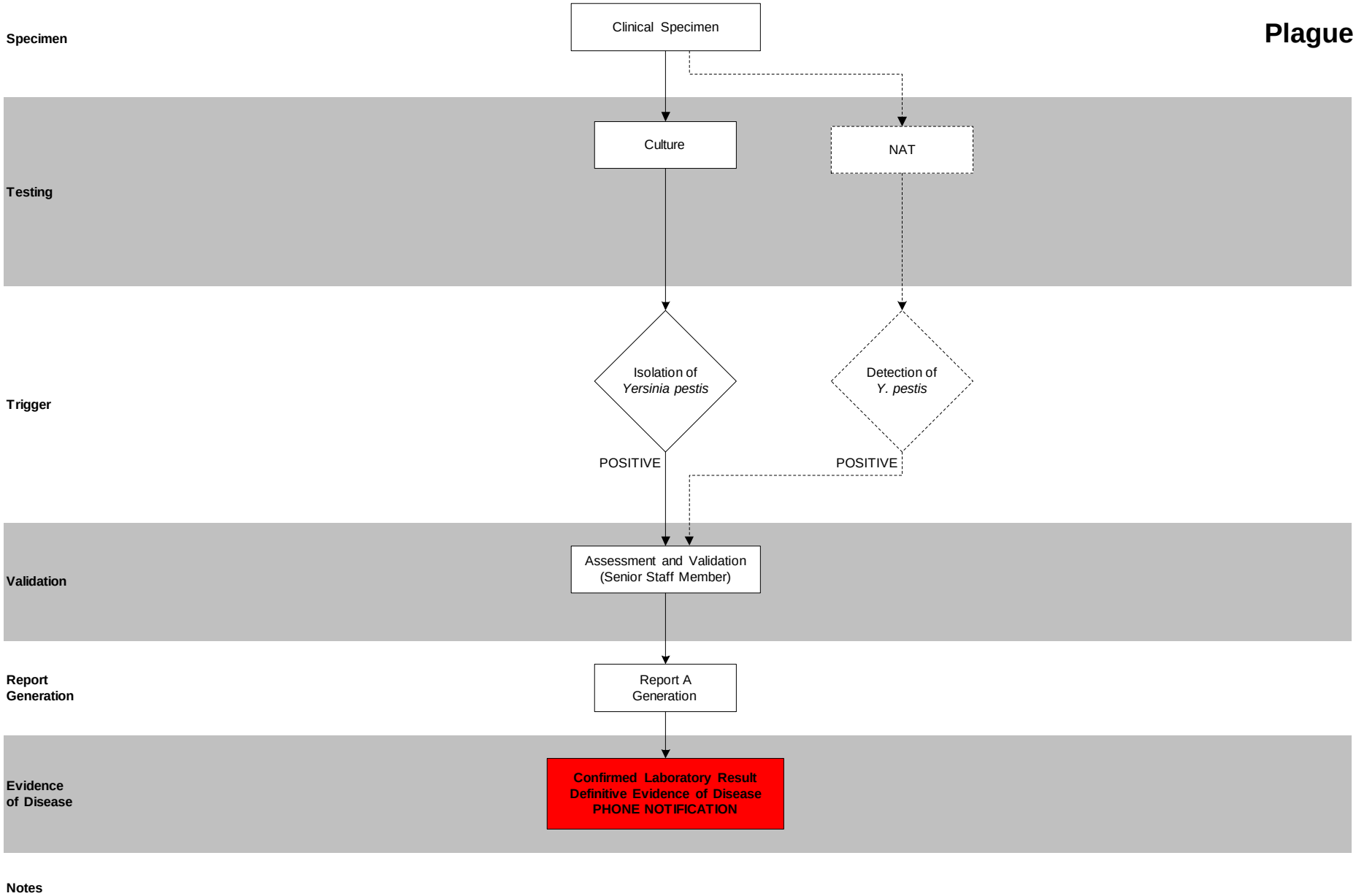
Notes 1 Seroconversion or significant increase in antibody level to mumps virus between acute and convalescent phase sera (tested in parallel at the same laboratory)

Pertussis (Whooping Cough)

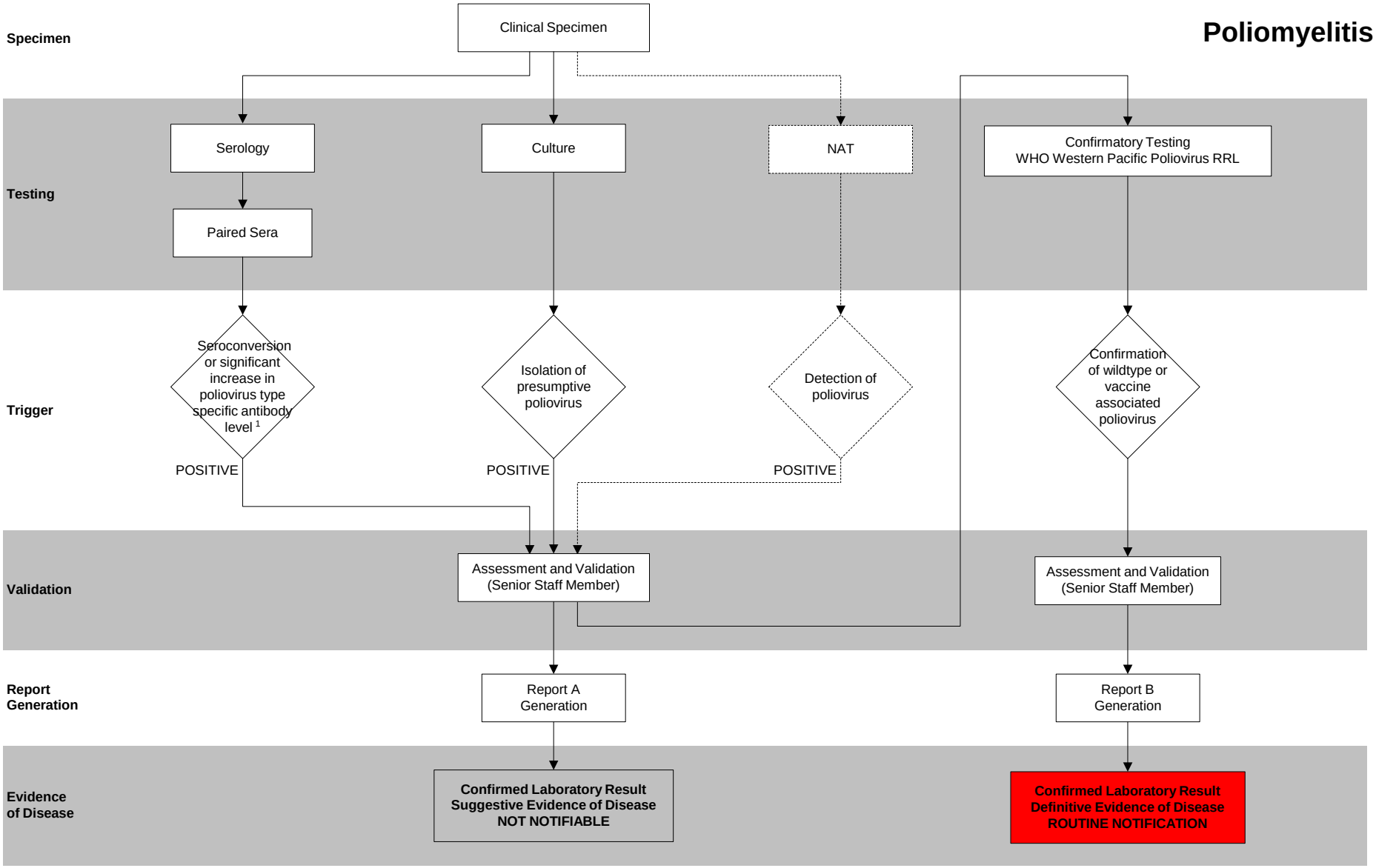


Notes 1 Seroconversion or significant increase in antibody level to *B. pertussis* between acute and convalescent phase sera (tested in parallel at the same laboratory)

Plague

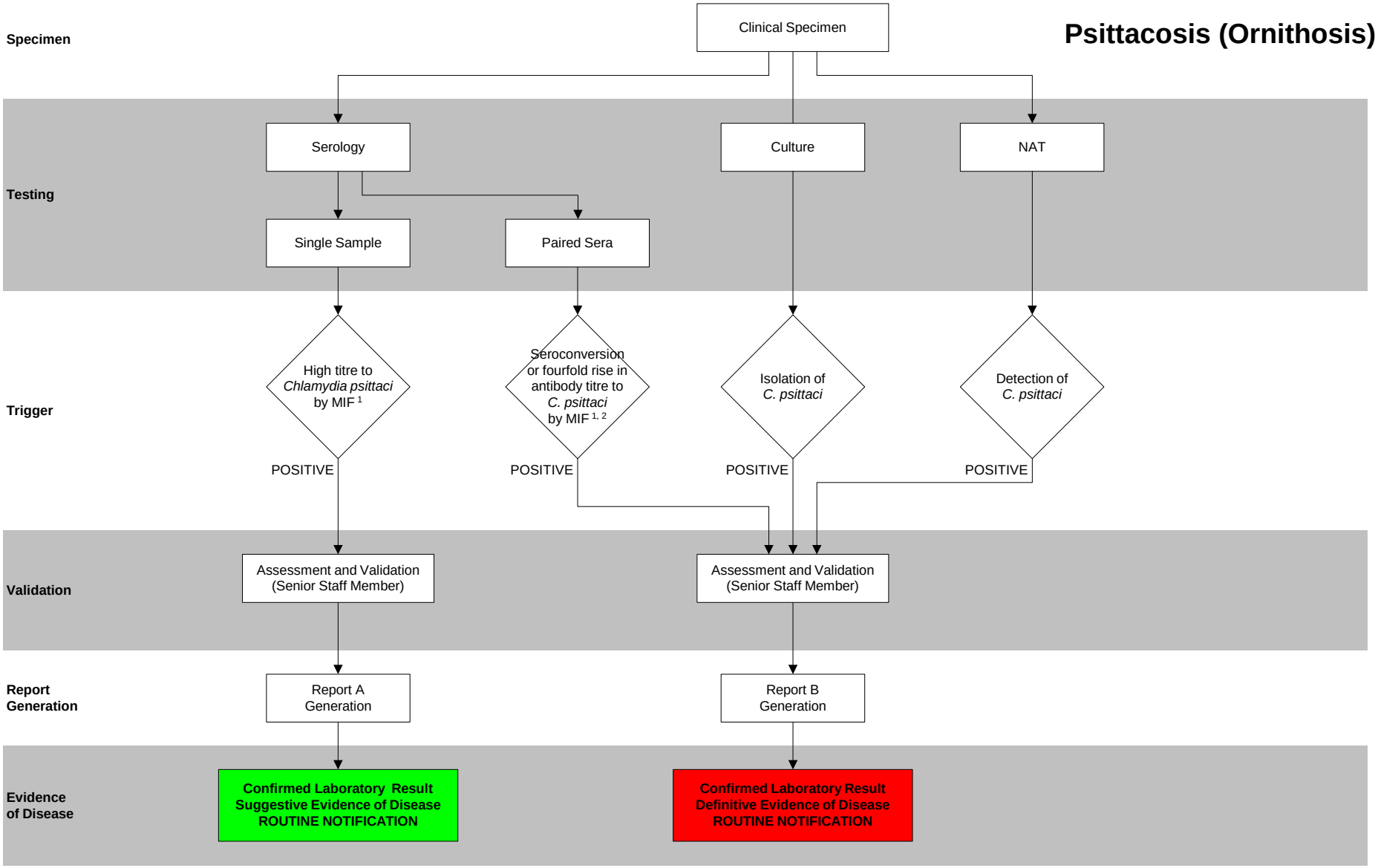

Specimen
Clinical Specimen
Testing
Culture
NAT
Trigger
Isolation of Yersinia pestis
Detection of Y. pestis
POSITIVE
POSITIVE
Validation
Assessment and Validation (Senior Staff Member)
Report Generation
Report A Generation
Evidence of Disease
Confirmed Laboratory Result
Definitive Evidence of Disease
PHONE NOTIFICATION
Notes

Poliomyelitis



Notes 1 Seroconversion or significant increase in poliovirus type specific antibody level between acute and convalescent phase sera (tested in parallel at the same laboratory)

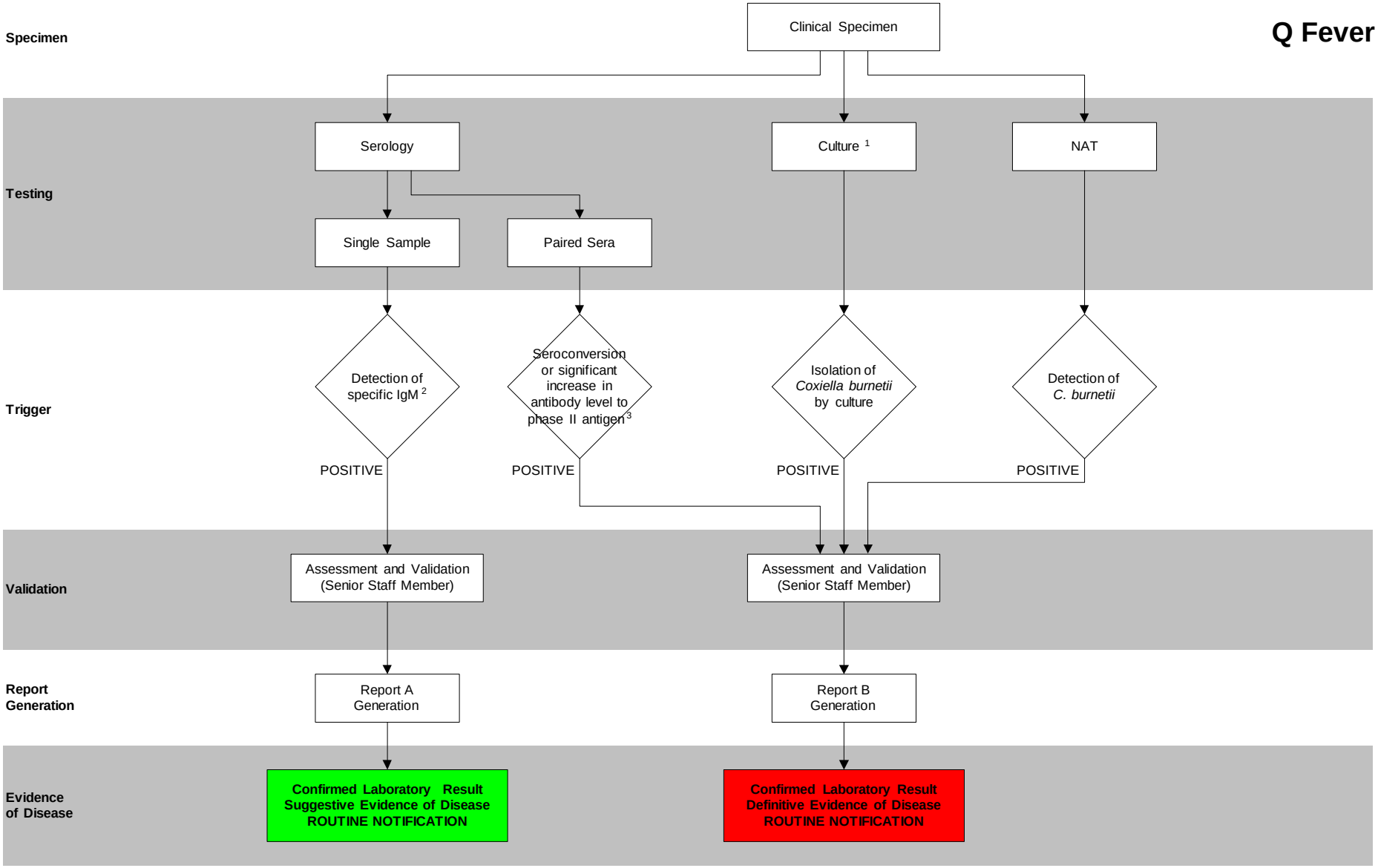
Psittacosis (Ornithosis)



Notes

1 In the absence of similar rises in antibody titre to other *Chlamydia* species
2 Seroconversion or fourfold or greater rise in MIF antibody titre to *Chlamydia psittaci* between acute and convalescent phase sera (tested in parallel at the same laboratory)

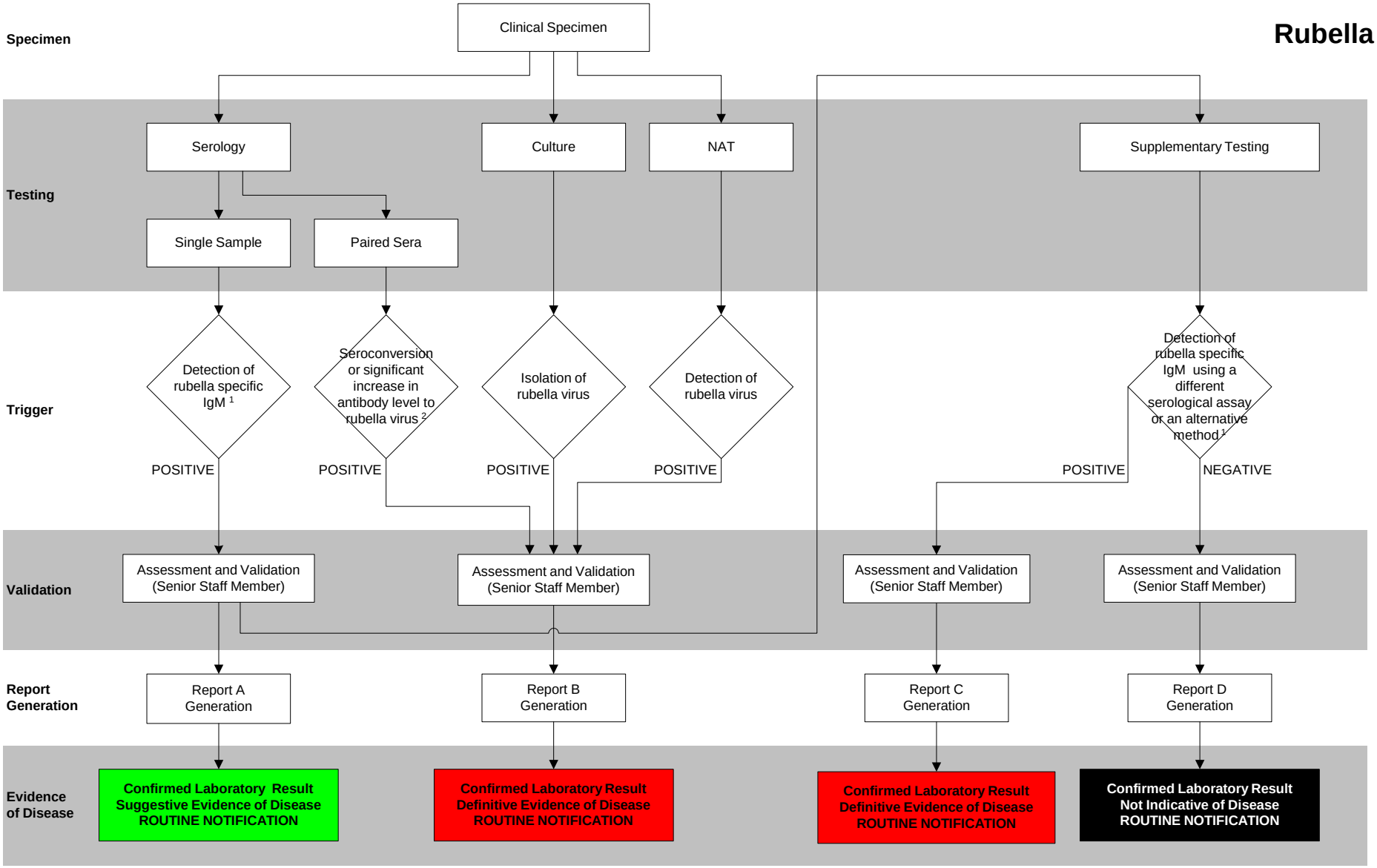
Q Fever



Notes

1 Culture should not be attempted except where appropriate facilities and training exist
2 IgM EIA testing has low specificity, diagnosis needs to be confirmed by more definitive methods
3 Seroconversion or significant increase in antibody level to phase II antigen in paired sera (tested in parallel at the same laboratory)

Rubella

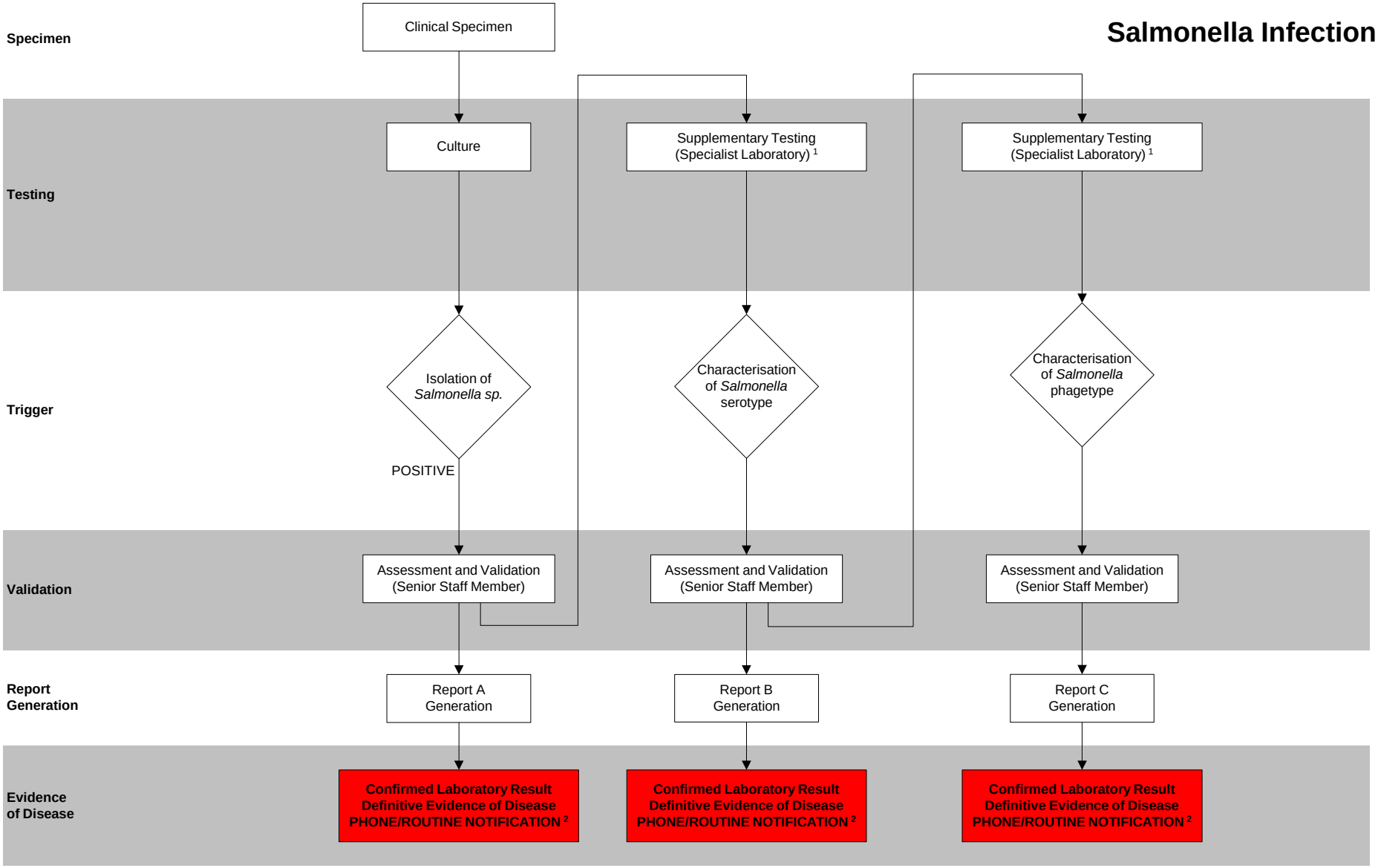


Notes

1 Supplementary IgM testing by a different serological assay or an alternative method, such as haemagglutination inhibition (HAI) on sucrose density gradient IgM fractions, is recommended in pregnancy

2 Seroconversion or significant increase in antibody level to rubella virus in paired sera (tested in parallel at the same laboratory)

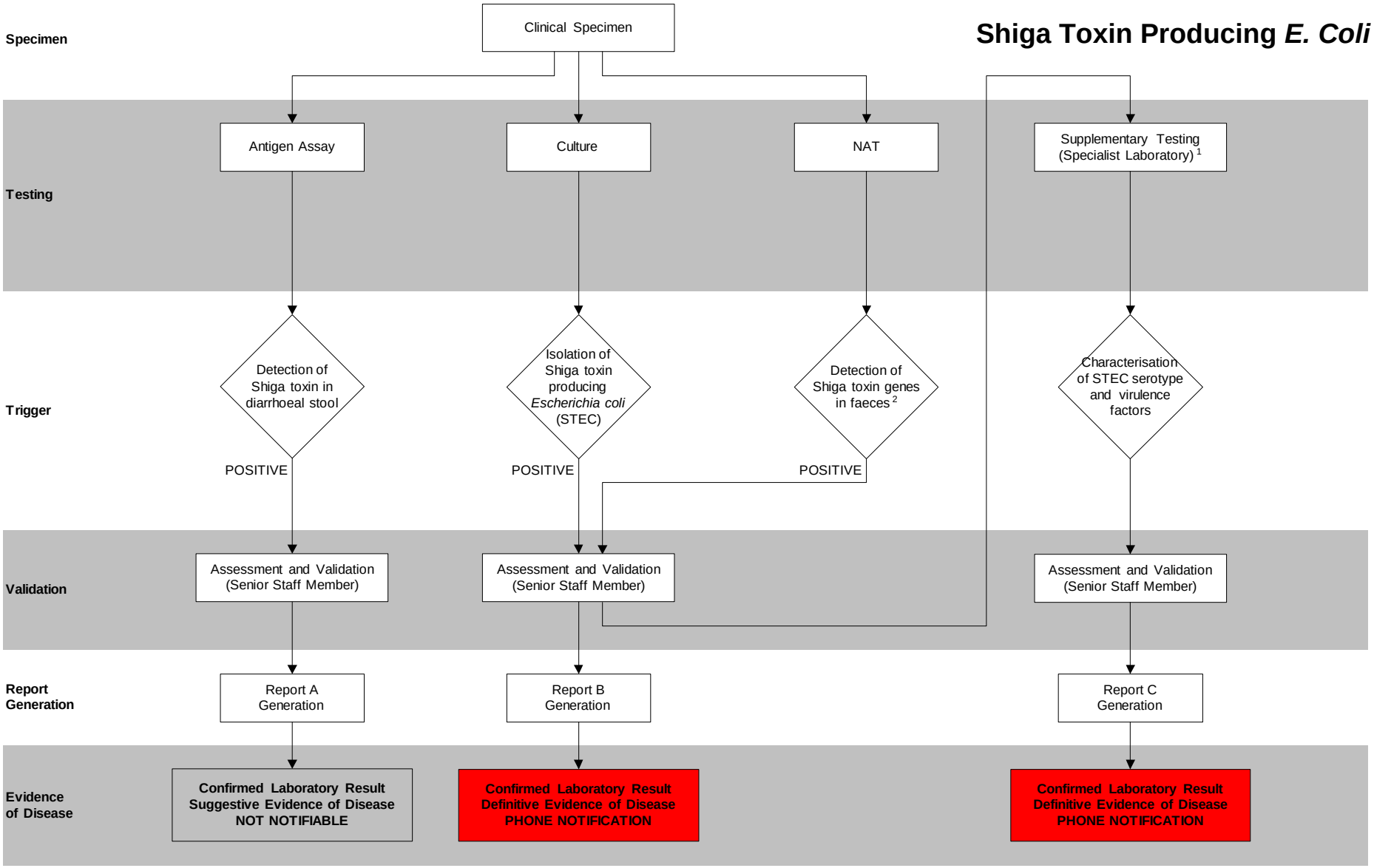
Salmonella Infection



Notes

1 All *Salmonella* isolates should be referred to a specialist laboratory for further characterisation
2 Typhoid is **PHONE** notifiable, *Salmonella* clusters and *Salmonella paratyphi* infections are **PHONE** notifiable, **ROUTINE** for all others

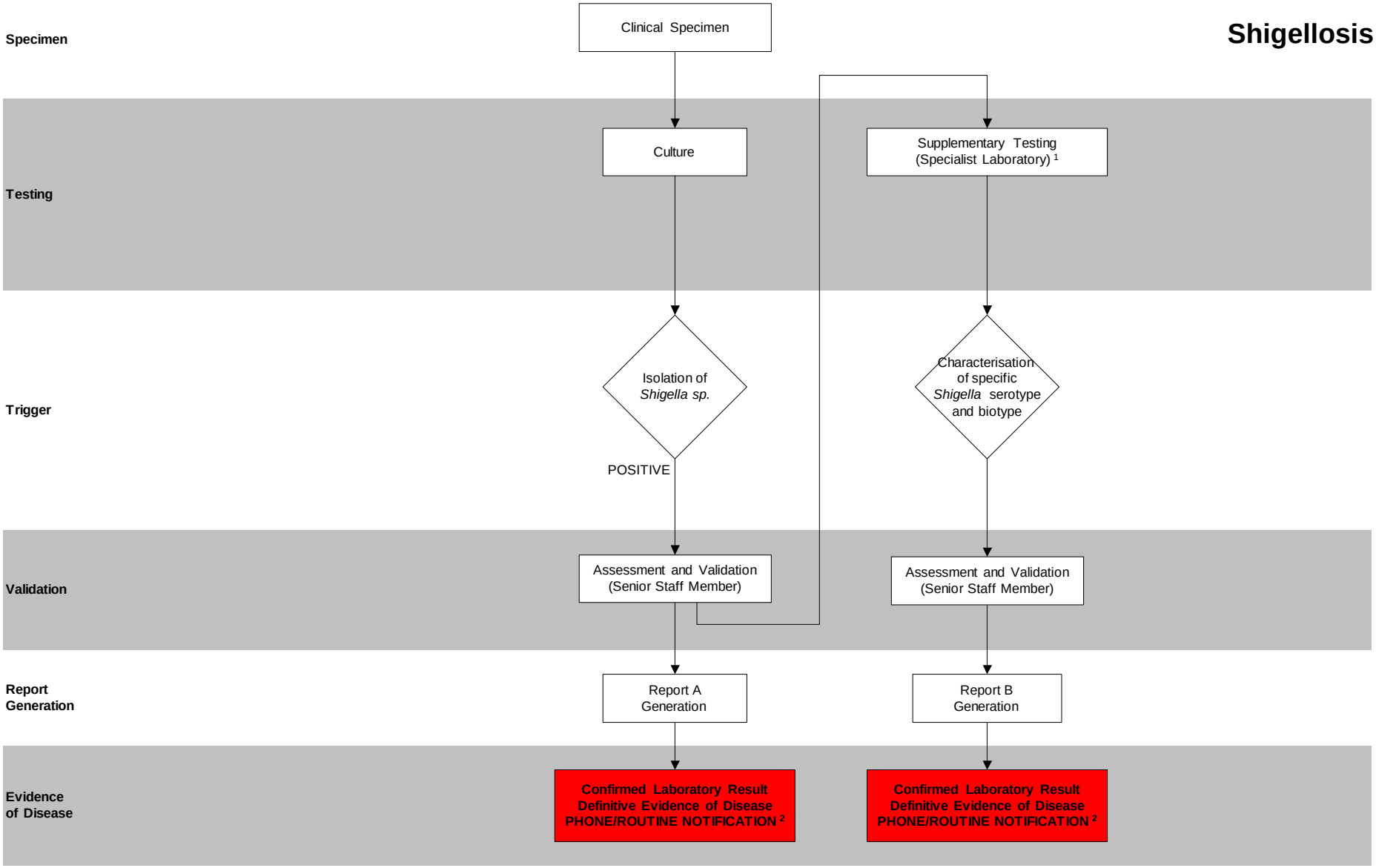
Shiga Toxin Producing *E. Coli*



Notes

1 All STEC isolates be referred to a specialist laboratory for further characterisation
2 By a validated NAT able to identify specific toxin sequences

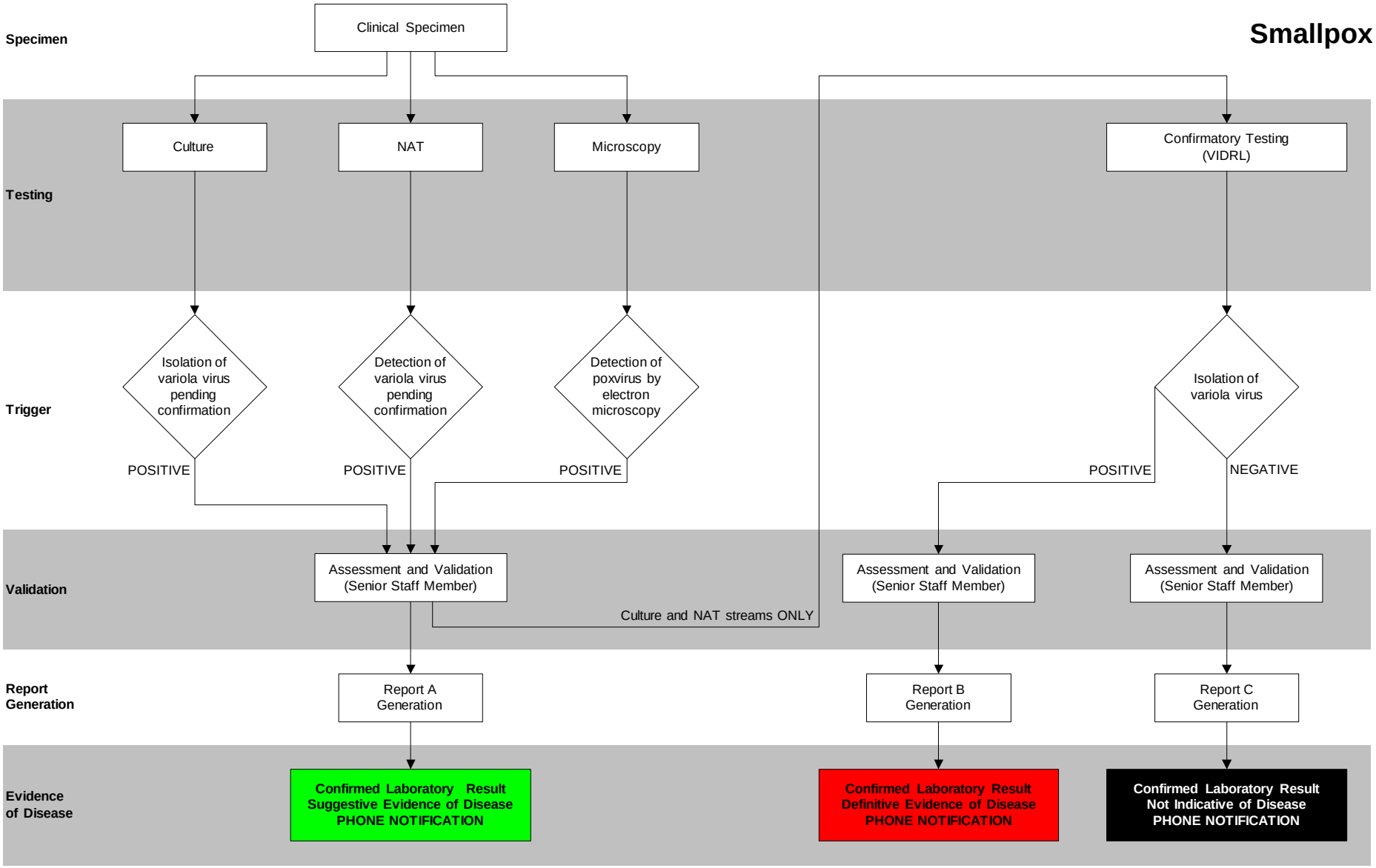
Shigellosis



Notes

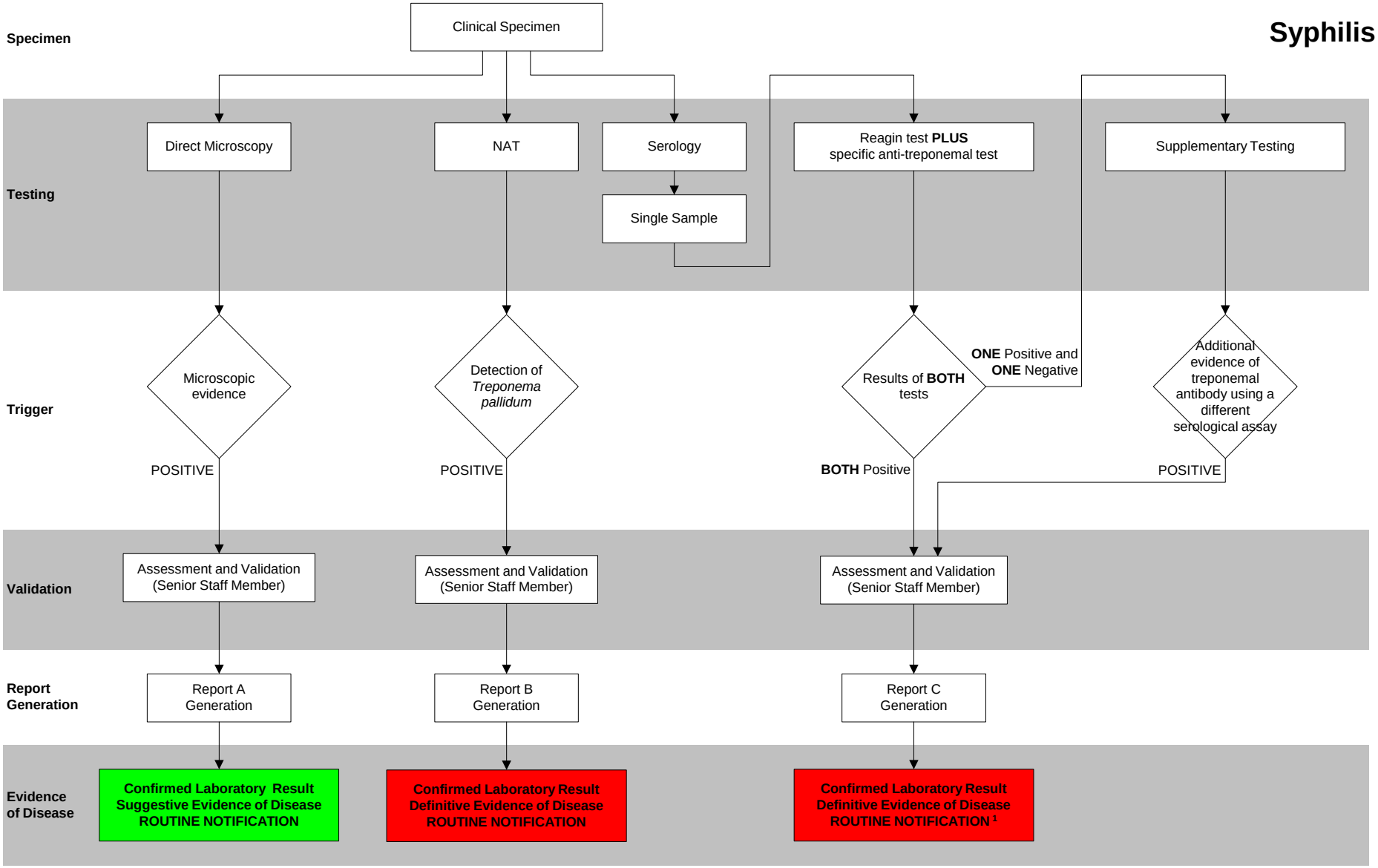
1 All *Shigella* isolates should be referred to a specialist laboratory for further characterisation
2 Clusters of *Shigella* are **PHONE** notifiable, **ROUTINE** for all others

Smallpox



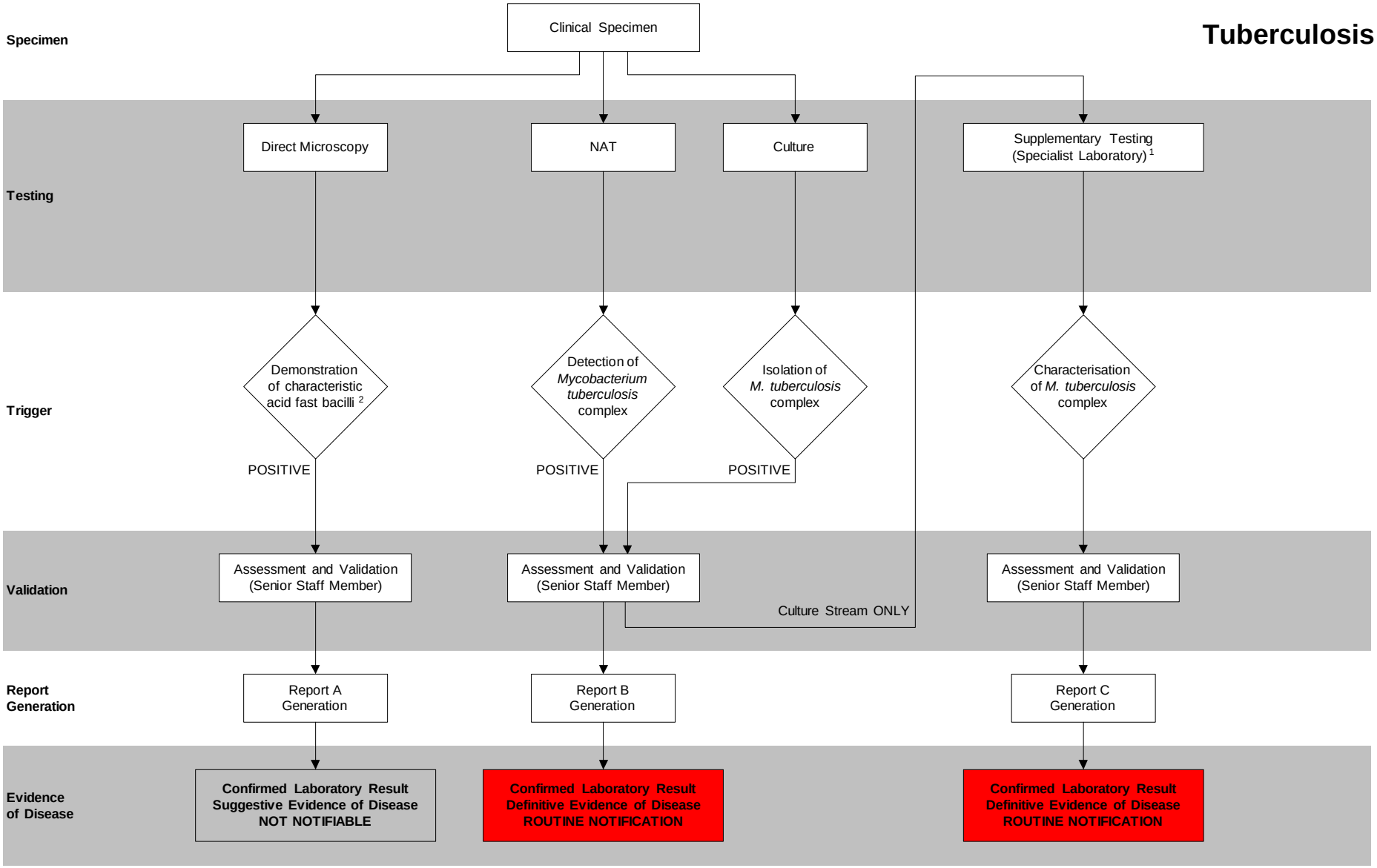
Notes Local testing protocols for smallpox may be modified according to the level of biothreat according to States and Territories smallpox response plans and the National Guidelines for Smallpox Outbreak, Preparedness, Response and Management (Jan 2004)

Syphilis



Notes 1 Full report required, including reagin test

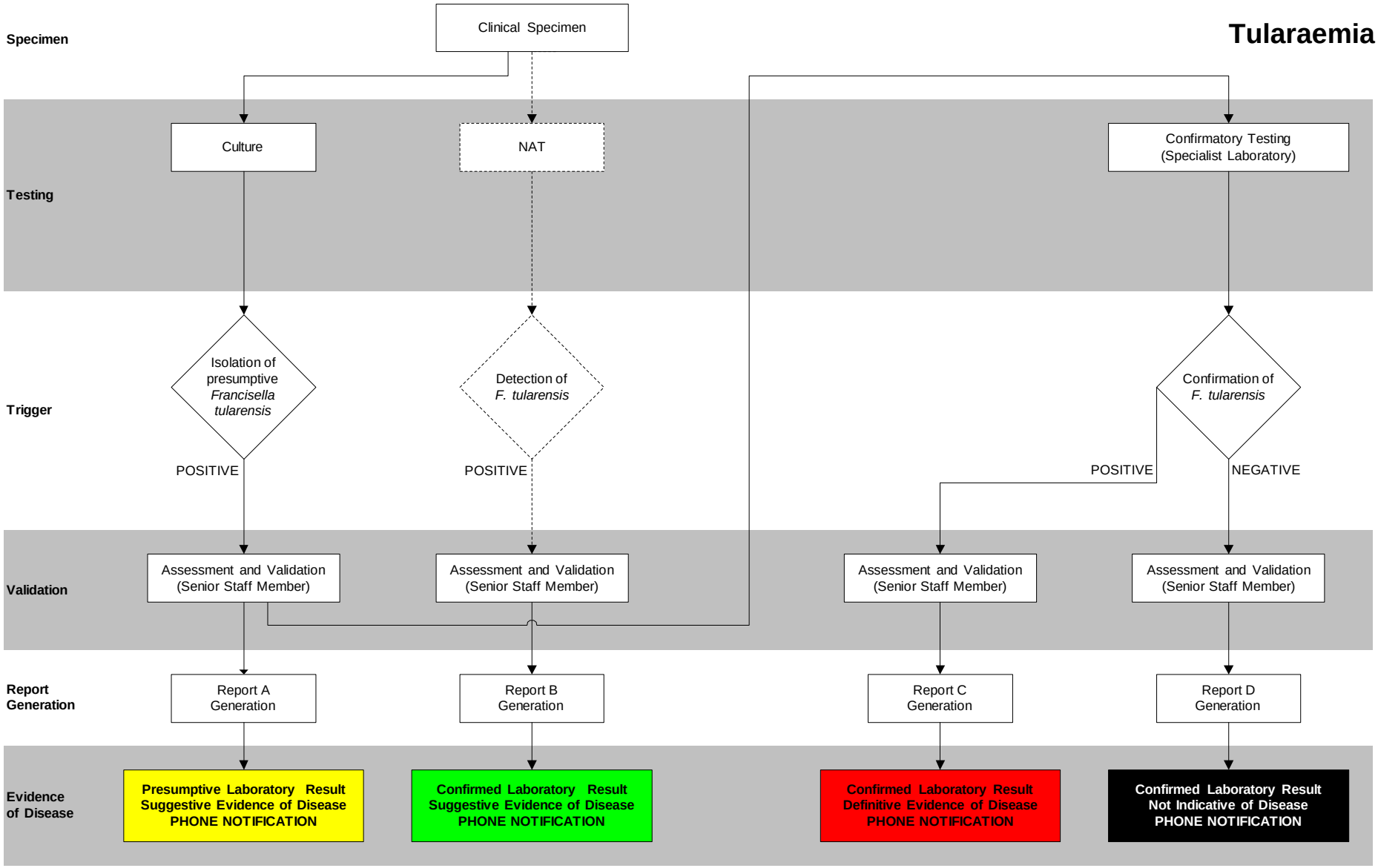
Tuberculosis



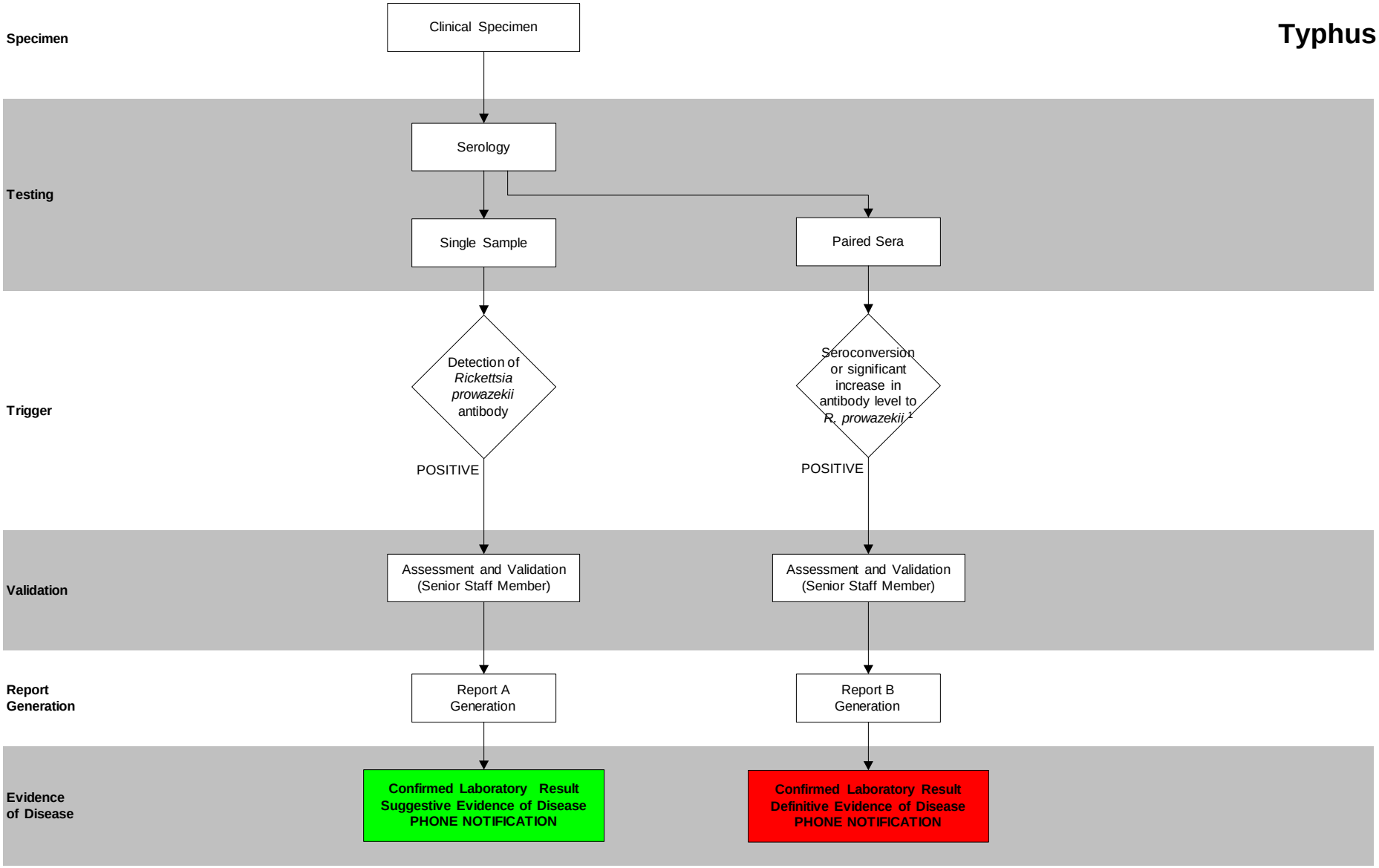
Notes

1 All *Mycobacterium tuberculosis* isolates (from the culture stream) should be referred to a specialist laboratory for further characterisation
2 Should be confirmed by culture

Tularaemia

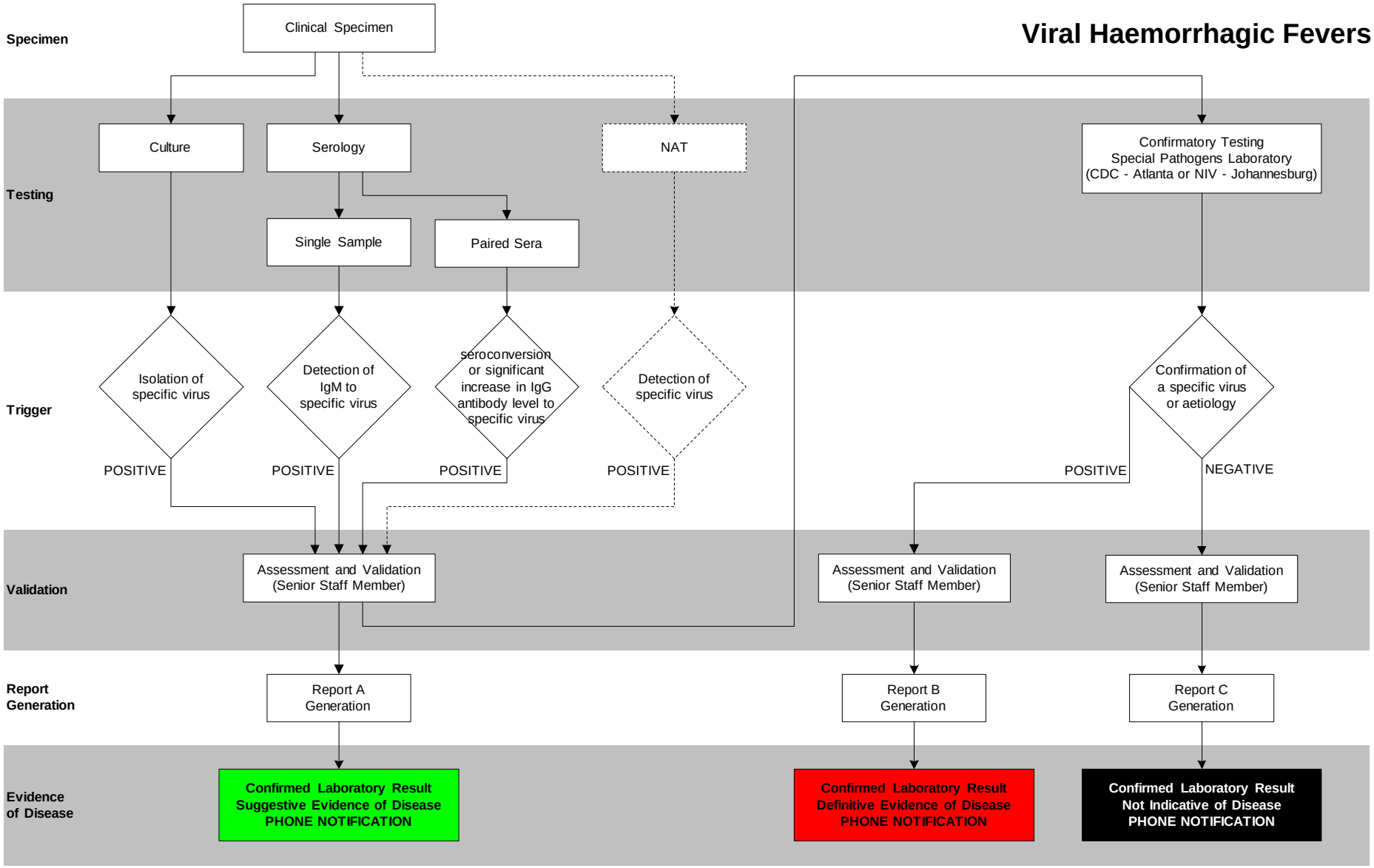

Specimen
Clinical Specimen
Testing
Culture
NAT
Confirmatory Testing
(Specialist Laboratory)
Trigger
Isolation of presumptive *Francisella tularensis*
Detection of *F. tularensis*
Confirmation of *F. tularensis*
POSITIVE
POSITIVE
POSITIVE
NEGATIVE
Validation
Assessment and Validation (Senior Staff Member)
Assessment and Validation (Senior Staff Member)
Assessment and Validation (Senior Staff Member)
Assessment and Validation (Senior Staff Member)
Report Generation
Report A Generation
Report B Generation
Report C Generation
Report D Generation
Evidence of Disease
Presumptive Laboratory Result Suggestive Evidence of Disease PHONE NOTIFICATION
Confirmed Laboratory Result Suggestive Evidence of Disease PHONE NOTIFICATION
Confirmed Laboratory Result Definitive Evidence of Disease PHONE NOTIFICATION
Confirmed Laboratory Result Not Indicative of Disease PHONE NOTIFICATION
Notes

Typhus

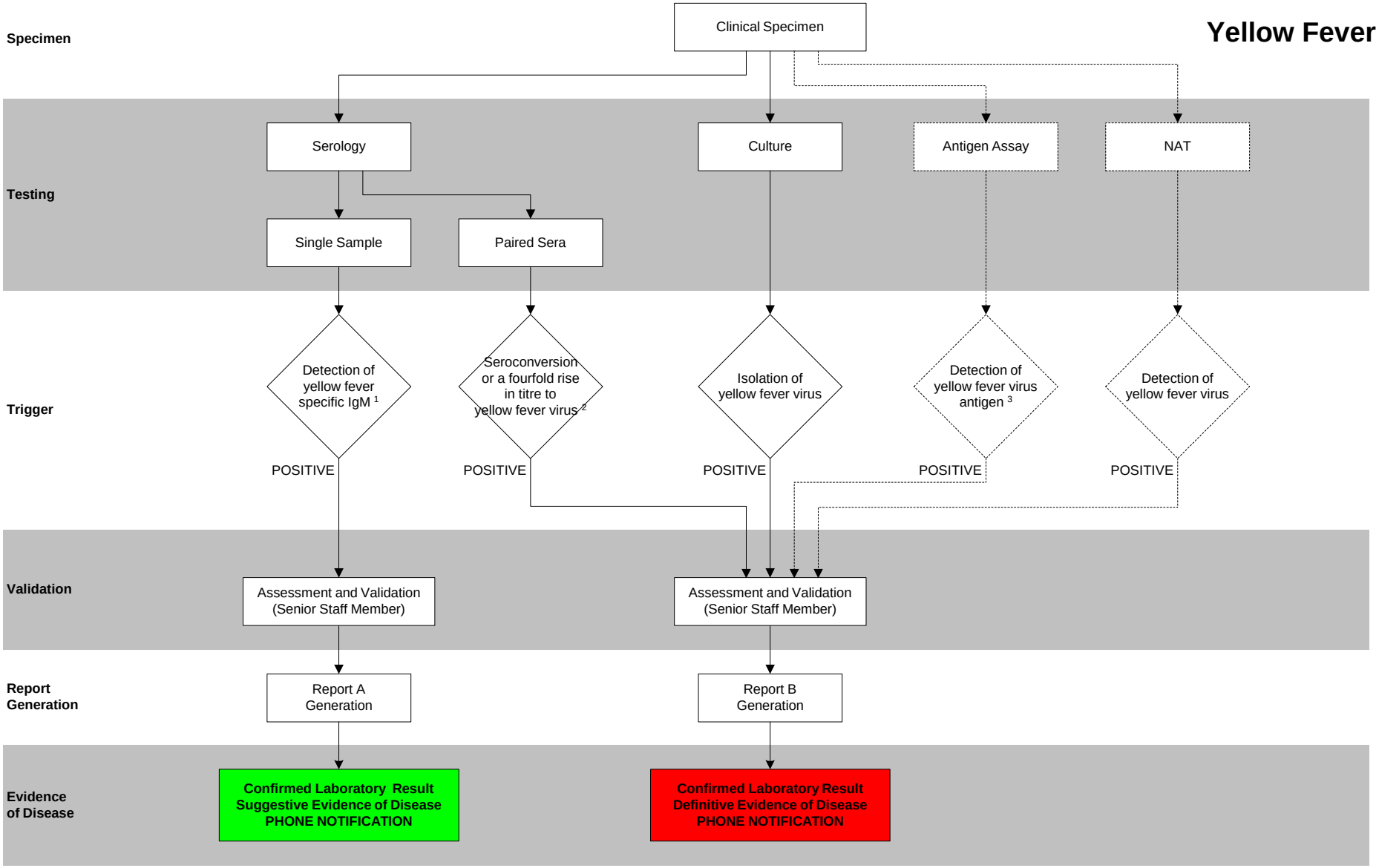


Notes 1 Seroconversion or significant increase in antibody level to *R. prowazekii* between acute and convalescent phase sera (tested in parallel at the same laboratory)

Viral Haemorrhagic Fevers



Yellow Fever



Notes

1 Detected in the absence of IgM to other flaviviruses
2 Seroconversion or fourfold rise in specific IgM or IgG titres to yellow fever virus between acute and convalescent phase sera (tested in parallel at the same laboratory)
3 In tissues by immunohistochemistry

SHPN: (PHD) 060076