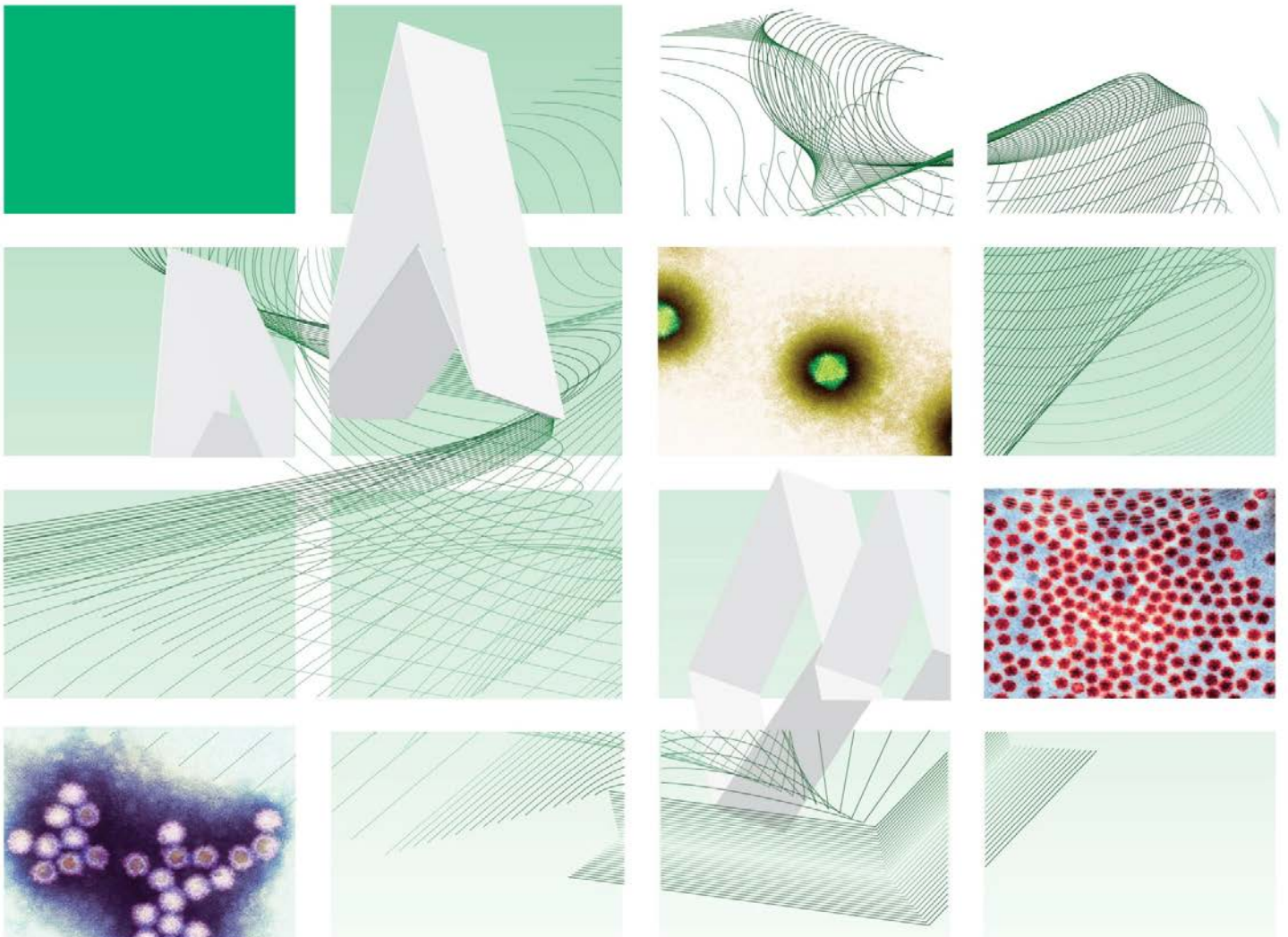




UK Standards for Microbiology Investigations

Investigation of Pregnant Women Exposed to Non-Vesicular Rash



Acknowledgments

UK Standards for Microbiology Investigations (SMIs) are developed under the auspices of Public Health England (PHE) working in partnership with the National Health Service (NHS), Public Health Wales and with the professional organisations whose logos are displayed below and listed on the website <https://www.gov.uk/uk-standards-for-microbiology-investigations-smi-quality-and-consistency-in-clinical-laboratories>. SMIs are developed, reviewed and revised by various working groups which are overseen by a steering committee (see <https://www.gov.uk/government/groups/standards-for-microbiology-investigations-steering-committee>).

The contributions of many individuals in clinical, specialist and reference laboratories who have provided information and comments during the development of this document are acknowledged. We are grateful to the Medical Editors for editing the medical content.

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UK Standards for Microbiology Investigations are produced in association with:



Logos correct at time of publishing.

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NICE has accredited the process used by Public Health England to produce Standards for Microbiology Investigations. Accreditation is valid for 5 years from July 2011. More information on accreditation can be viewed at www.nice.org.uk/accreditation.

For full details on our accreditation visit: www.nice.org.uk/accreditation.

Amendment Table

Each SMI method has an individual record of amendments. The current amendments are listed on this page. The amendment history is available from standards@phe.gov.uk.

New or revised documents should be controlled within the laboratory in accordance with the local quality management system.

Amendment No/Date.	7/02.02.15
Issue no. discarded.	4.2
Insert Issue no.	5
Section(s) involved	Amendment
Whole document.	Hyperlinks updated to gov.uk.
Page 2.	Updated logos added.
Whole document.	Title changed to Investigation of Pregnant Women Exposed to Non-Vesicular Rash. Erythrovirus replaced with Parvovirus throughout.
Contents.	'Pregnant Patient In Contact With Rash Illness' algorithm removed.
Scope.	Inclusion of a scope to the document, which includes type of specimen and definition of terms. Addition of links to relevant SMIs.
Algorithms.	B19V, Rubella and Measles algorithms updated and renamed for clarity (additional information on repeat testing, referral and advice if symptoms appear). Removal of IgM from measles algorithm.
Footnotes.	All footnotes updated and additional footnotes included.
References.	Some references updated.

UK Standards for Microbiology Investigations[#]: Scope and Purpose

Users of SMIs

- SMIs are primarily intended as a general resource for practising professionals operating in the field of laboratory medicine and infection specialties in the UK.
- SMIs provide clinicians with information about the available test repertoire and the standard of laboratory services they should expect for the investigation of infection in their patients, as well as providing information that aids the electronic ordering of appropriate tests.
- SMIs provide commissioners of healthcare services with the appropriateness and standard of microbiology investigations they should be seeking as part of the clinical and public health care package for their population.

Background to SMIs

SMIs comprise a collection of recommended algorithms and procedures covering all stages of the investigative process in microbiology from the pre-analytical (clinical syndrome) stage to the analytical (laboratory testing) and post analytical (result interpretation and reporting) stages.

Syndromic algorithms are supported by more detailed documents containing advice on the investigation of specific diseases and infections. Guidance notes cover the clinical background, differential diagnosis, and appropriate investigation of particular clinical conditions. Quality guidance notes describe laboratory processes which underpin quality, for example assay validation.

Standardisation of the diagnostic process through the application of SMIs helps to assure the equivalence of investigation strategies in different laboratories across the UK and is essential for public health surveillance, research and development activities.

Equal Partnership Working

SMIs are developed in equal partnership with PHE, NHS, Royal College of Pathologists and professional societies.

The list of participating societies may be found at <https://www.gov.uk/uk-standards-for-microbiology-investigations-smi-quality-and-consistency-in-clinical-laboratories>.

Inclusion of a logo in an SMI indicates participation of the society in equal partnership and support for the objectives and process of preparing SMIs. Nominees of professional societies are members of the Steering Committee and Working Groups which develop SMIs. The views of nominees cannot be rigorously representative of the members of their nominating organisations nor the corporate views of their organisations. Nominees act as a conduit for two way reporting and dialogue. Representative views are sought through the consultation process.

SMIs are developed, reviewed and updated through a wide consultation process.

[#]Microbiology is used as a generic term to include the two GMC-recognised specialties of Medical Microbiology (which includes Bacteriology, Mycology and Parasitology) and Medical Virology.

Quality Assurance

NICE has accredited the process used by the SMI Working Groups to produce SMIs. The accreditation is applicable to all guidance produced since October 2009. The process for the development of SMIs is certified to ISO 9001:2008.

SMIs represent a good standard of practice to which all clinical and public health microbiology laboratories in the UK are expected to work. SMIs are NICE accredited and represent neither minimum standards of practice nor the highest level of complex laboratory investigation possible. In using SMIs, laboratories should take account of local requirements and undertake additional investigations where appropriate. SMIs help laboratories to meet accreditation requirements by promoting high quality practices which are auditable. SMIs also provide a reference point for method development.

The performance of SMIs depends on competent staff and appropriate quality reagents and equipment. Laboratories should ensure that all commercial and in-house tests have been validated and shown to be fit for purpose. Laboratories should participate in external quality assessment schemes and undertake relevant internal quality control procedures.

Patient and Public Involvement

The SMI Working Groups are committed to patient and public involvement in the development of SMIs. By involving the public, health professionals, scientists and voluntary organisations the resulting SMI will be robust and meet the needs of the user. An opportunity is given to members of the public to contribute to consultations through our open access website.

Information Governance and Equality

PHE is a Caldicott compliant organisation. It seeks to take every possible precaution to prevent unauthorised disclosure of patient details and to ensure that patient-related records are kept under secure conditions.

The development of SMIs are subject to PHE Equality objectives <https://www.gov.uk/government/organisations/public-health-england/about/equality-and-diversity>. The SMI Working Groups are committed to achieving the equality objectives by effective consultation with members of the public, partners, stakeholders and specialist interest groups.

Legal Statement

Whilst every care has been taken in the preparation of SMIs, PHE and any supporting organisation, shall, to the greatest extent possible under any applicable law, exclude liability for all losses, costs, claims, damages or expenses arising out of or connected with the use of an SMI or any information contained therein. If alterations are made to an SMI, it must be made clear where and by whom such changes have been made.

The evidence base and microbial taxonomy for the SMI is as complete as possible at the time of issue. Any omissions and new material will be considered at the next review. These standards can only be superseded by revisions of the standard, legislative action, or by NICE accredited guidance.

SMIs are Crown copyright which should be acknowledged where appropriate.

Suggested Citation for this Document

Public Health England. (2015). Investigation of Pregnant Women Exposed to Non-Vesicular Rash. UK Standards for Microbiology Investigations. V 30 Issue 5.
<https://www.gov.uk/uk-standards-for-microbiology-investigations-smi-quality-and-consistency-in-clinical-laboratories>

Scope of Document

Type of specimen

Blood, serum, oral fluid, throat swab, vesicle swab, urine

Scope

This algorithm covers the investigation of samples from immunocompetent pregnant women exposed to non-vesicular (maculopapular) rashes, and can be used to investigate possible contact with the following viruses:

- Parvovirus B19 (fifth disease, erythema infectiosum, slapped cheek syndrome)
- Rubella virus (German measles)
- Rubeola virus (measles)

The algorithms assume that immunisation status has been determined from the vaccination record and/or serology results. A person is considered immune if they are immunocompetent and either have had two doses of a vaccine that protects against rubella and measles or have laboratory evidence of prior immunity¹. Where immunisation history or prior tests suggest no immunity, or immune status is unknown, proceed to testing algorithms. A stored antenatal booking sample may be used for convenience.

A specific cause for maculopapular rash illness is rarely investigated or confirmed. Therefore, for pregnant contacts of maculopapular rash illness, investigation of parvovirus B19, rubella and measles immunity may be considered in parallel if clinically indicated. Respiratory symptoms (coryza, sneezing, cough) are prominent, early features of measles in infection for the majority of patients. These symptoms, if recorded in the patients' notes, may be used to differentiate measles from parvovirus B19 and rubella infection. Regardless of a request for specific rubella or parvovirus B19 testing, PHE guidance recommends that pregnant women should be simultaneously investigated for immunity to both infections unless their immune status is already known². If however, the contact patient has a laboratory diagnosed rash is no need to test for both infections.

If immunisation history or tests indicate immunity to all viruses under investigation, reassure the patient but advise her to seek medical advice if she develops symptoms. Pregnant women should report all rashes, regardless of known immunity or vaccination status.

This document is restricted to viruses with clear management intervention during pregnancy. The following viral pathogens cause rash illness, but are not included in this algorithm:

- Varicella Zoster Virus (VZV) (chicken pox and shingles)
- Enterovirus
- Herpes Simplex Virus (HSV)
- Human Herpes Virus 6 and 7 (HHV 6 and 7)
- Cytomegalovirus (CMV)

- Epstein-Barr Virus (EBV)

Enterovirus, human herpes virus 6 and 7, and Epstein-Barr virus are not associated with congenital infection syndromes. Varicella zoster virus, herpes simplex virus and cytomegalovirus are associated with congenital infection; information regarding these viruses can be found in the SMIs listed below.

For further information regarding rash in pregnancy, refer to the PHE document “Guidance on Viral Rash in Pregnancy”

<https://www.gov.uk/government/publications/viral-rash-in-pregnancy>, the “National Measles Guidelines” <https://www.gov.uk/government/publications/national-measles-guidelines>,

and the Department of Health Green Book ‘Immunisation against infectious diseases’ (<https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>)¹⁻⁴. Guidelines from the devolved nations are also available^{5,6}.

For clinical guidance regarding the investigation of rubella, measles, parvovirus B19, enterovirus and other viruses which cause red rash refer to [G 7 – Investigation of Red Rash](#).

For clinical guidance regarding varicella zoster virus (VZV) including chicken pox (varicella) and shingles (herpes zoster) refer to [G 6 – Investigation of Vesicular Rashes](#).

For information regarding cytomegalovirus serology refer to [V 28 - Cytomegalovirus Serology](#).

This SMI should be used in conjunction with other SMIs (<https://www.gov.uk/government/collections/standards-for-microbiology-investigations-smi>).

Definitions

For all antigen, antibody and NAATs testing the following definitions apply:

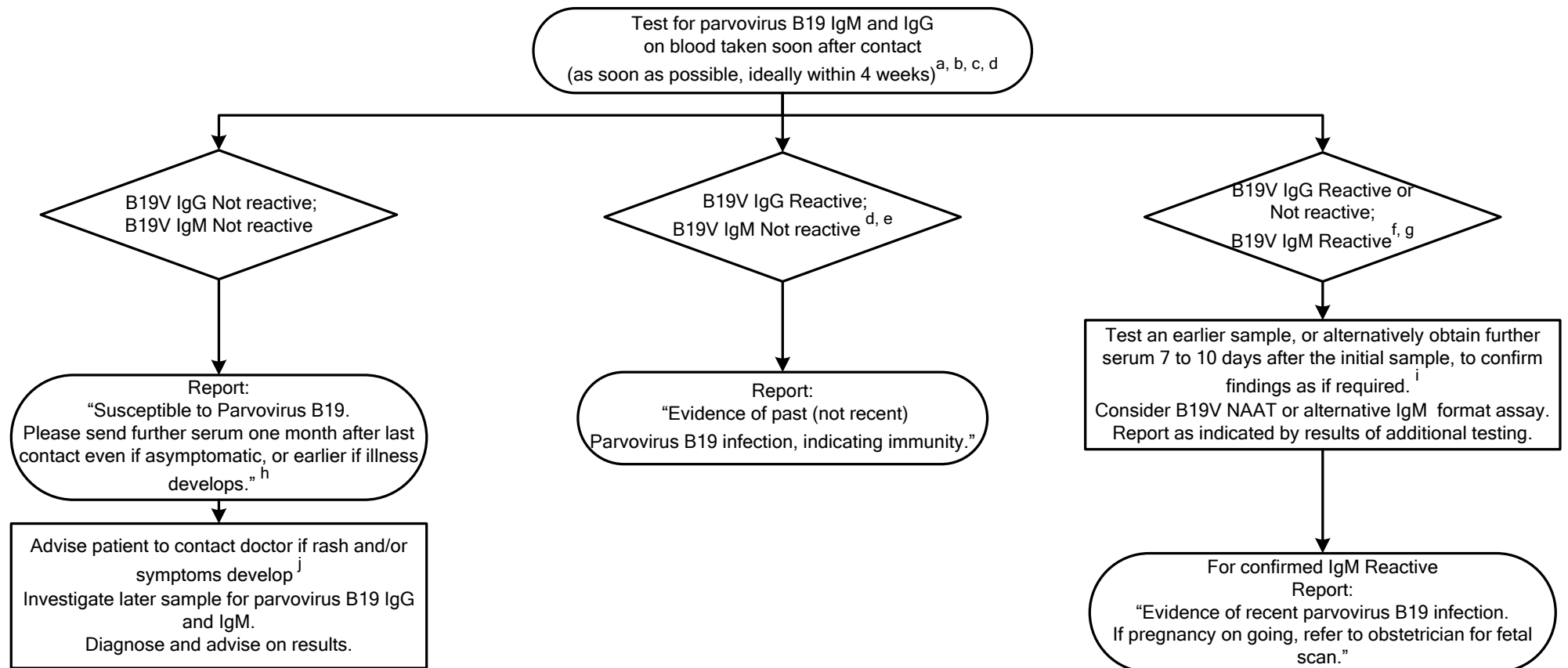
Reactive – Initial internal-stage positive result pending confirmation.

Not reactive - Initial internal-stage negative result.

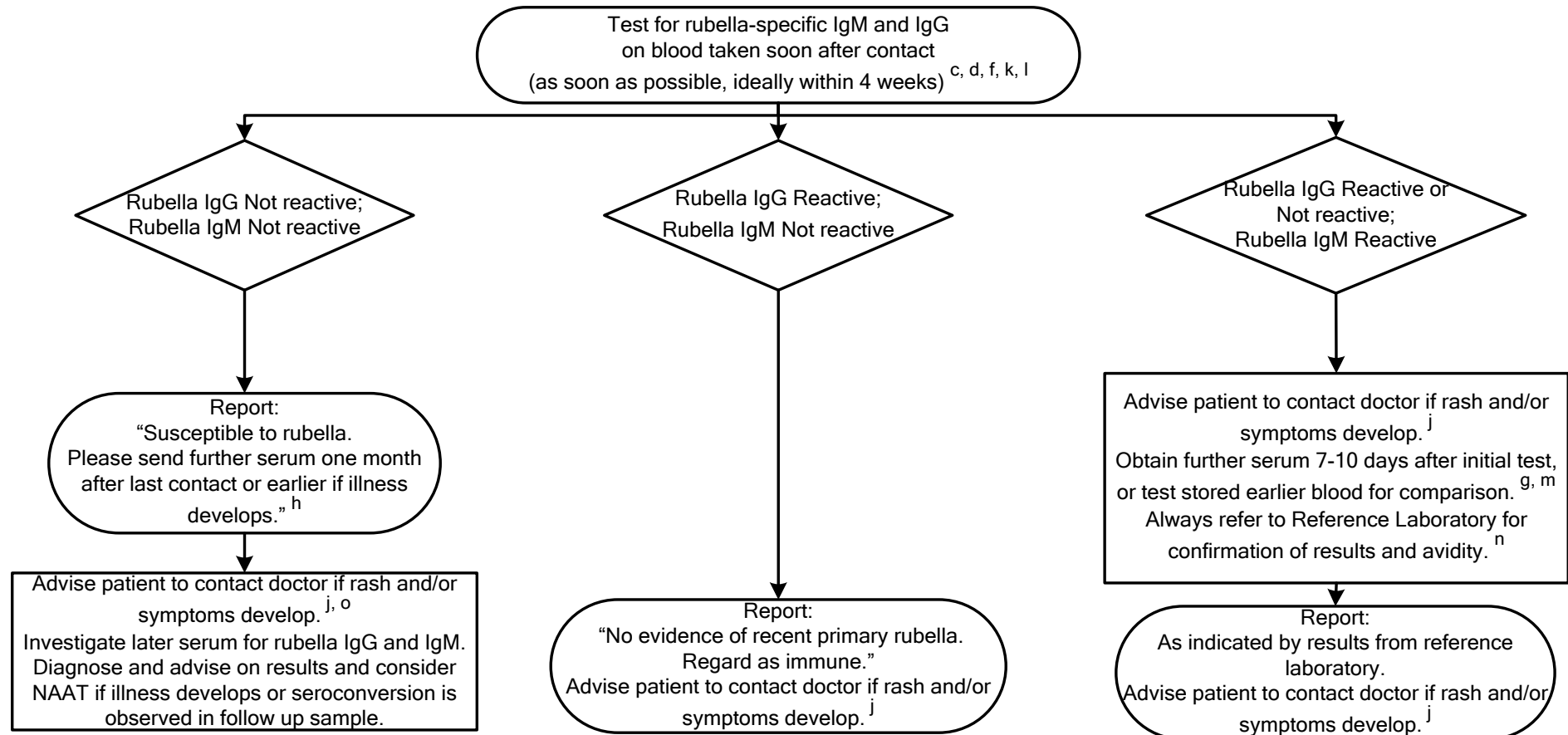
Detected – Report-stage confirmed reactive result.

Not detected – Report-stage not reactive result.

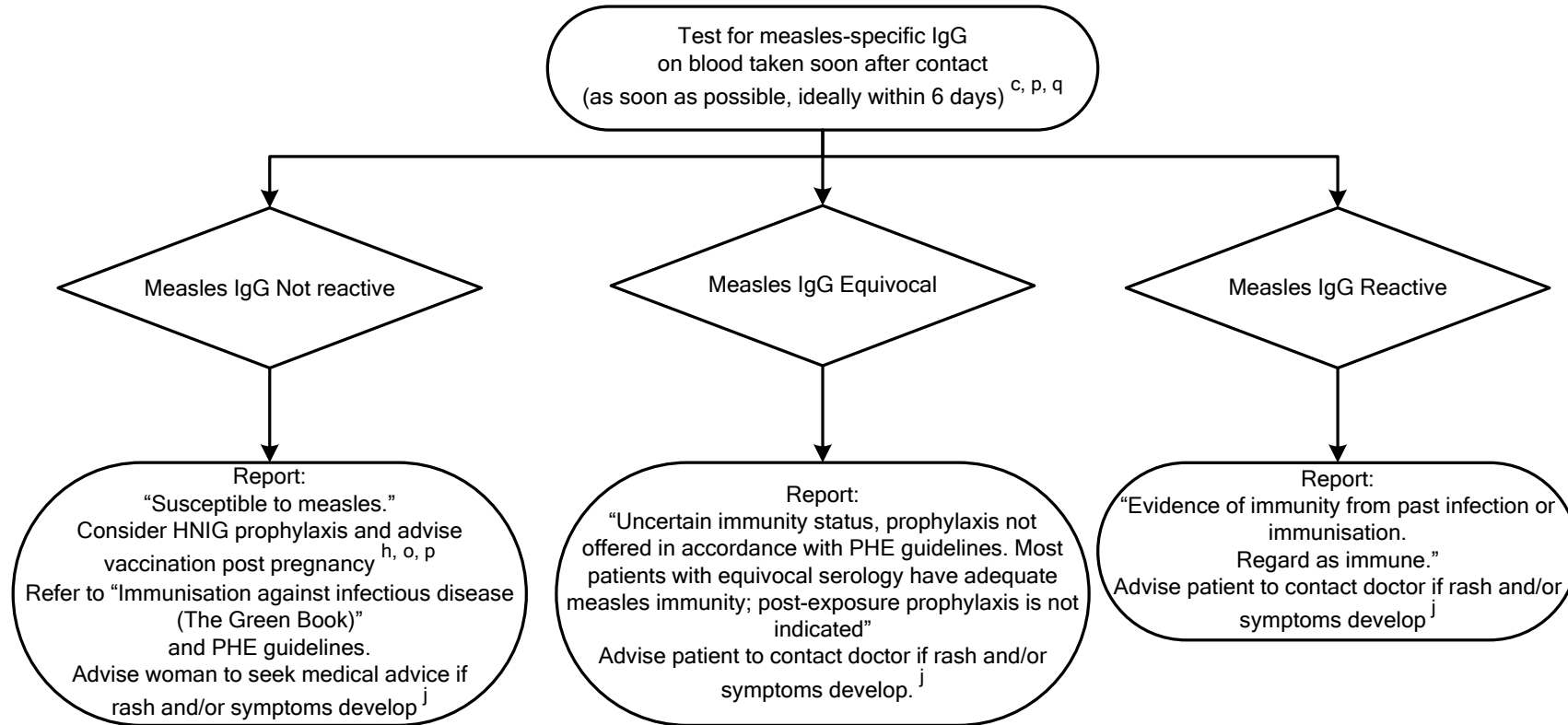
Investigation of Parvovirus B19 (B19V) in Pregnant Women Exposed to Non-Vesicular Rash



Investigation of Rubella in Pregnant Women Exposed to Non-Vesicular Rash (who have no evidence of past infection or full immunisation)



Investigation of Measles in Pregnant Women Exposed to Rash Consistent with/Confirmed as Measles (who have no evidence of past infection or full immunisation)



Footnotes

- a) Patients infected with parvovirus B19 are considered non-infectious one day after the rash begins.
- b) The risks of fetal loss and hydrops fetalis are highest when parvovirus B19 infection occurs within the first 20 weeks of gestation. If exposed after 20 weeks gestation the risks of fetal damage are low, but the testing algorithm should still be followed. Determining the date of infection can be difficult in the absence of maternal illness, but may be possible using retrospective testing of testing of earlier samples.
- c) If available, rather than requesting a current sample, consider testing an earlier sample (eg booking blood), taken ≥ 4 weeks before reporting rash contact, for IgG. If IgG positive, reassure the patient.
- d) If contact is declared \geq one month after exposure, a negative IgM result may not exclude relatively recent infection. If possible test earlier sample.
- e) In some patients testing an earlier sample may detect unrecognised earlier infections in pregnancy.
- f) In some patients IgM may be persistent. In these situations testing an earlier sample may assist diagnosis by demonstrating presence or absence of seroconversion.
- g) Caution should be taken when interpreting IgM results; low reactivity is often non-specific. Consider testing for potential cross reacting IgM and for recent EBV infection.
- h) Advise patient to avoid contact with other pregnant women and to inform clinical staff of contact when attending medical areas, until known to be uninfected.
- i) If confirmation is delayed, an interim report may be required. Interim reports based on low level activity IgM results should state that low reactivity may be non-specific.
- j) Based on clinical assessment, pregnant women who develop a rash consistent with infection should be referred to a fetal medicine specialist by their doctor.
- k) This algorithm refers to pregnant women whose immunisation status to rubella is unknown or unconfirmed². If a pregnant women is regarded as immune (see footnote c) they can be reassured that the risk of rubella infection is remote but that they are to return for testing if relevant illness (rash, arthralgia) develops^{1,2}.
- l) The risk of severe congenital defect with rubella virus occurs predominantly when infection happens within the first 16 weeks of gestation, although cases of deafness may result from infection occurring between 16 and 20 weeks. If exposed beyond 16-20 weeks, reassure the patient. However continue testing to confirm the date of infection relative to gestational age⁷.
- m) If an earlier sample has tested as IgG negative and seroconversion has occurred; further investigation is required.

- n) Primary rubella is uncommon in the UK and most initial reactive IgM results are false. Interim reports should not usually be issued until reference laboratory confirmation of IgM reactivity and IgG avidity has been done.
- o) A two dose course of MMR vaccine is advised on completion of pregnancy if the woman is confirmed as susceptible².
- p) In susceptible pregnant women, HNIG prophylaxis will be issued up to 6 days after exposure^{4,5}.
- q) IgG results from tests carried out ≥ 10 days after exposure cannot be interpreted in this clinical scenario.

Notification to PHE^{8,9} or Equivalent in the Devolved Administrations¹⁰⁻¹³

The Health Protection (Notification) regulations 2010 require diagnostic laboratories to notify Public Health England (PHE) when they identify the causative agents that are listed in Schedule 2 of the Regulations. Notifications must be provided in writing, on paper or electronically, within seven days. Urgent cases should be notified orally and as soon as possible, recommended within 24 hours. These should be followed up by written notification within seven days.

For the purposes of the Notification Regulations, the recipient of laboratory notifications is the local PHE Health Protection Team. If a case has already been notified by a registered medical practitioner, the diagnostic laboratory is still required to notify the case if they identify any evidence of an infection caused by a notifiable causative agent.

Notification under the Health Protection (Notification) Regulations 2010 does not replace voluntary reporting to PHE. The vast majority of NHS laboratories voluntarily report a wide range of laboratory diagnoses of causative agents to PHE and many PHE Health protection Teams have agreements with local laboratories for urgent reporting of some infections. This should continue.

Note: The Health Protection Legislation Guidance (2010) includes reporting of Human Immunodeficiency Virus (HIV) & Sexually Transmitted Infections (STIs), Healthcare Associated Infections (HCAs) and Creutzfeldt–Jakob disease (CJD) under 'Notification Duties of Registered Medical Practitioners': it is not noted under 'Notification Duties of Diagnostic Laboratories'.

<https://www.gov.uk/government/organisations/public-health-england/about/our-governance#health-protection-regulations-2010>

Other arrangements exist in [Scotland](#)^{10,11}, [Wales](#)¹² and [Northern Ireland](#)¹³.

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