

NATIONAL STANDARD METHOD

INVESTIGATION OF SWINE- LINEAGE INFLUENZA A/H1N1 v USING THE SWINE-LINEAGE INFLUENZA A H1 ASSAY

VSOP 51

Issued by Standards Unit, Department for Evaluations, Standards and Training
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UK Clinical Virology Network

Association of Medical Microbiologists
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INVESTIGATION OF SWINE-LINEAGE INFLUENZA A/H1N1 v USING THE SWINE-LINEAGE INFLUENZA A H1 ASSAY
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STATUS OF NATIONAL STANDARD METHODS

National Standard Methods, which include standard operating procedures (SOPs), algorithms and guidance notes, promote high quality practices and help to assure the comparability of diagnostic information obtained in different laboratories. This in turn facilitates standardisation of surveillance underpinned by research, development and audit and promotes public health and patient confidence in their healthcare services. The methods are well referenced and represent a good minimum standard for clinical and public health microbiology. However, in using National Standard Methods, laboratories should take account of local requirements and may need to undertake additional investigations. The methods also provide a reference point for method development.

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Representatives of several professional organisations, including those whose logos appear on the front cover, are members of the working groups which develop National Standard Methods. Inclusion of an organisation's logo on the front cover implies support for the objectives and process of preparing standard methods. The representatives participate in the development of the National Standard Methods but their views are not necessarily those of the entire organisation of which they are a member. The current list of participating organisations can be obtained by emailing standards@hpa.org.uk.

The performance of standard methods depends on the quality of reagents, equipment, commercial and in-house test procedures. Laboratories should ensure that these have been validated and shown to be fit for purpose. Internal and external quality assurance procedures should also be in place.

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The reader is informed that all taxonomy in this document was correct at time of issue.

Please note the references are now formatted using Reference Manager software. If you alter or delete text without Reference Manager installed on your computer, the references will not be updated automatically.

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AMENDMENT PROCEDURE

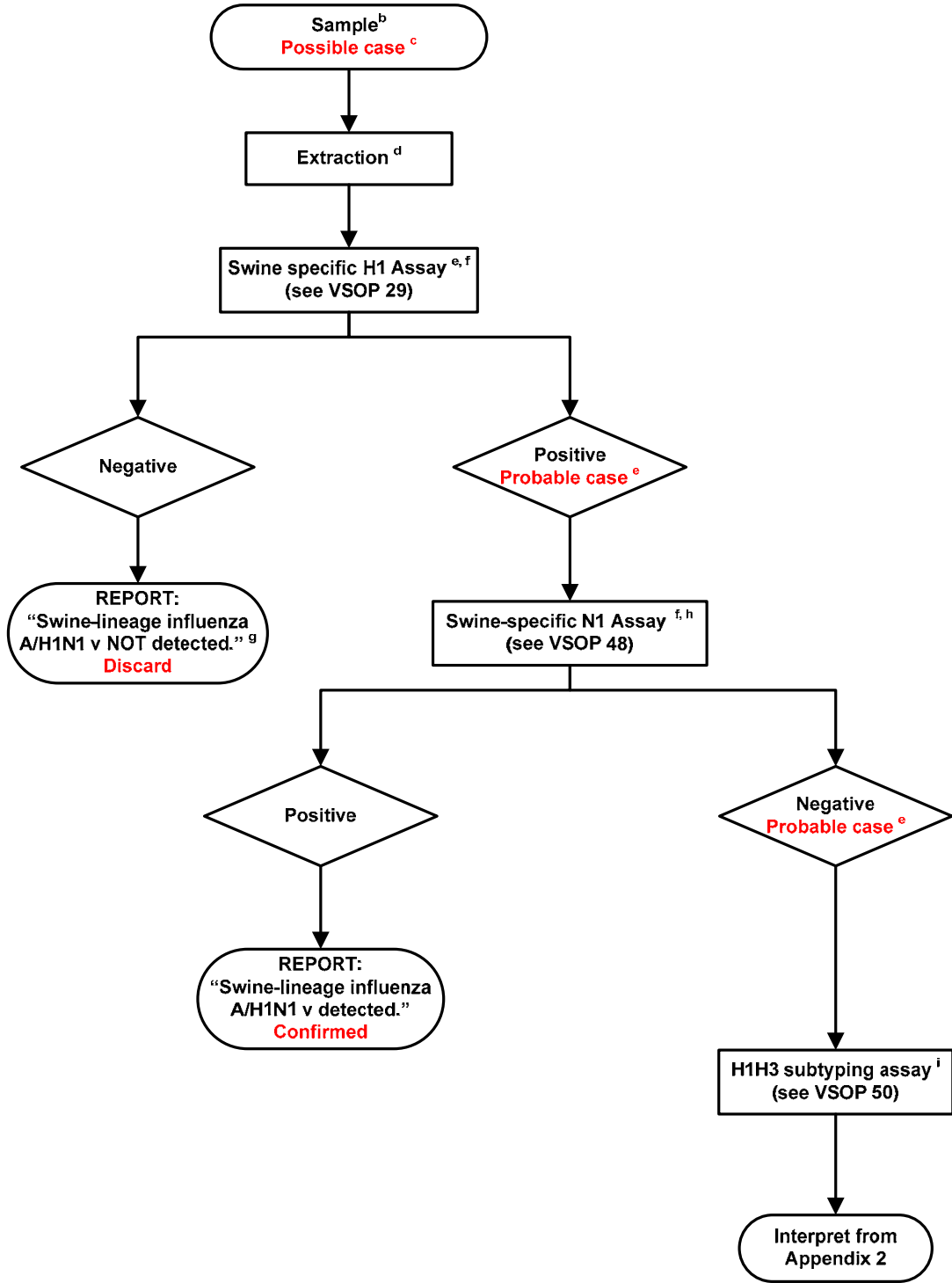
Controlled document reference	VSOP 51
Controlled document title	Investigation of Swine-lineage Influenza A/H1N1 v using the Swine-lineage Influenza A H1 assay

Each National Standard Method has an individual record of amendments. The current amendments are listed on this page. The amendment history is available from standards@hpa.org.uk.

On issue of revised or new pages each controlled document should be updated by the copyholder in the laboratory.

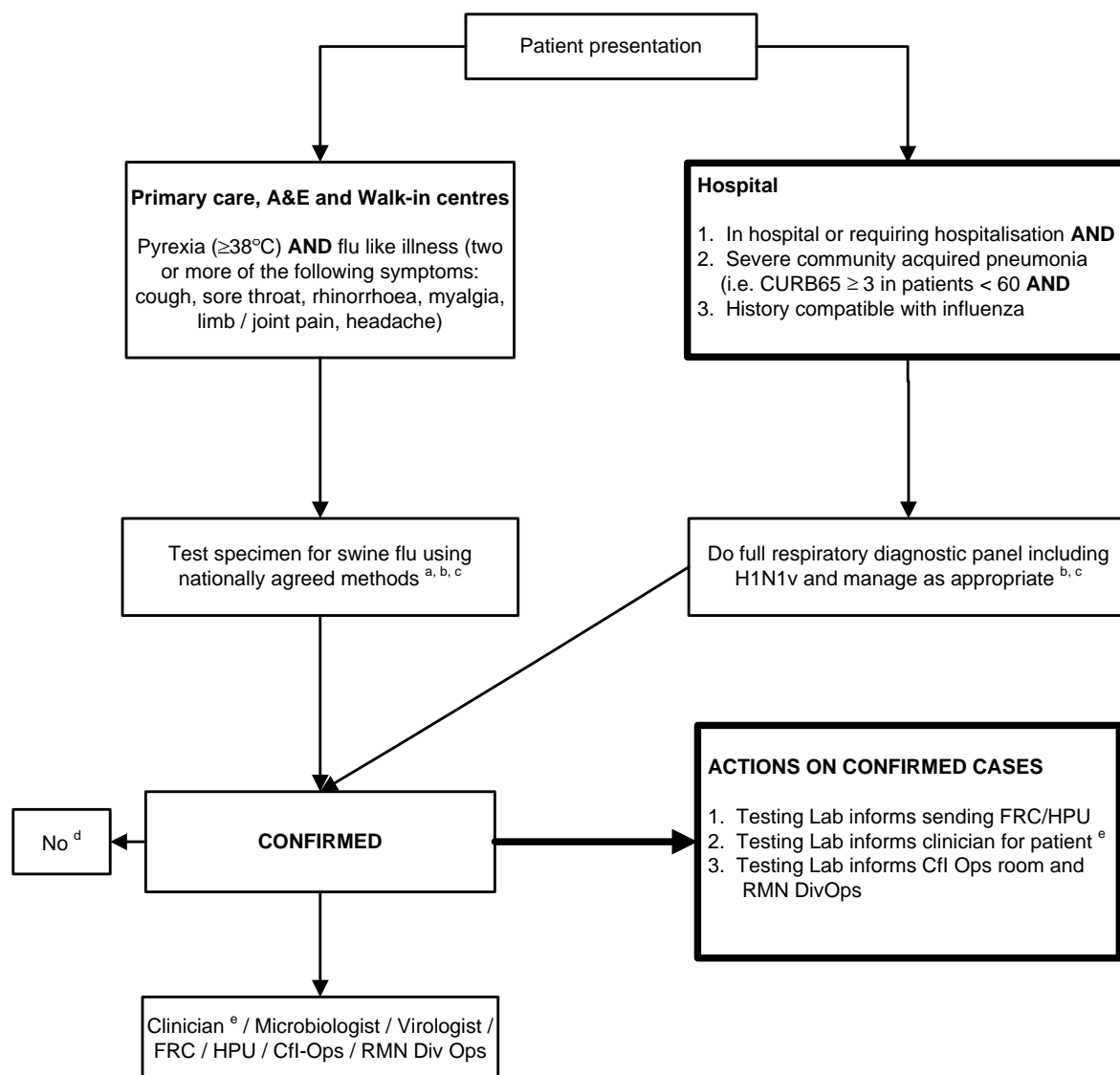
Amendment Number/ Date	Issue no. Discarded	Insert Issue no.	Page	Section(s) involved	Amendment

INVESTIGATION OF SWINE-LINEAGE INFLUENZA A/H1N1 v USING THE SWINE-LINEAGE INFLUENZA A H1 ASSAY ^a



- a This approach to testing, using a swine-specific assay as the frontline test, is suitable for dealing with large numbers of samples to exclude swine-lineage influenza A/H1N1 v, and in laboratories in mitigation phase in a swine-lineage influenza A/H1N1v outbreak. Although the algorithm is written showing sequential H1 then N1 testing it is equally valid to do both H1 and N1 tests simultaneously as frontline tests.
- b Samples should be collected and sent to the laboratory in appropriate packaging (Class B packaging). Samples will usually be nose and throat swabs combined into virus transport medium (see HPA guidance on sample collection and transport: 'Standard practical advice for investigating individuals with possible swine influenza infection' available at www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1241048770758). Samples should be sent to a designated laboratory by approved courier. In the laboratory samples are to be treated as Hazard Group 2 specimens unless from known infected individuals, in which case they must be handled in a Class 1 or Class 2 Biological Safety Cabinet in a Category 2 laboratory (or at Category 3 containment if liquid samples such as sputum or NPA)².
- c This algorithm refers to investigation where the case definition is met or where surveillance for swine-lineage influenza A/H1N1 v has been undertaken. Case definitions are found on the HPA website as 'Swine Influenza case definition' at www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1241048739571. Definitions may change, so refer to above and to the latest algorithms. S5 algorithm on the HPA website [www.hpa.org.uk](http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1240732819361), (http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1240732819361) and S5b (http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1244023923195).
- d Samples may be inactivated by heating at 80°C for 20 minutes.
- e Swine-Lineage Influenza A H1 Specific Fast Real Time PCR – see [VSOP29 – Swine-Lineage Influenza A H1 specific fast Real Time PCR](#) (available for password holders on request at www.hpa-standardmethods.org.uk). Note that the assay is validated for extraction using Qiagen QIAamp® Viral RNA Mini kit or Biomerieux NucliSENS® easy MAG. Also note that there is a potential for false negative results if the sample is inhibitory to PCR.
- f Note that the run control provided for the HPA real-time PCR assays is a genetically distinct positive control virus (A/Aragon/3218/2008); false positives due to contamination with this virus can be readily differentiated by sequencing from true positives.
- g Consider testing for non-swine influenza A as well as influenza B and other respiratory viruses.
- h [Swine-lineage influenza A N1 real time confirmatory PCR assay – see VSOP48](#) (available for password holders on request at www.hpa-standardmethods.org.uk) or similar generic influenza A matrix assay nucleic acid amplification test.
- i [One-Step Influenza Multiplex Real Time RT-PCR \(Influenza A H1H3 Subtype assay\) – see VSOP 50](#)

APPENDIX 1 – MANAGEMENT OF CONFIRMED AND PROBABLE CASES



^a Subject to review depending on changing circumstances – suitable approaches may vary from laboratory to laboratory, but frontline testing using H1v and N1v PCRs may have benefits when testing for swine-lineage influenza A/H1N1 v only is needed

^b There is no need to contact the laboratory to inform them that samples are being sent

^c Please do not contact laboratories directly for results - results will be fed back through agreed channels (this request also applies to patients)

^d Manage as clinically indicated

^e This may vary from region to region subject to local agreement with HPUs

APPENDIX 2 – SWINE INFLUENZA A/H1N1 v REPORTING MATRIX

Profile	Testing Sequence (left to right)				Report	Action
	Swine H1	Swine N1	Subtype H1H3	Repeat Swine H1		
1	Negative				Swine-lineage Influenza A/H1N1 v NOT detected	None – discard Consider testing for non-swine influenza A and other respiratory pathogens
2	Positive	Positive			Swine-lineage Influenza A/H1N1 v Detected. Confirmed case	Communicate result. Send sample to Cfl
3*	Positive				Compatible with Swine-lineage Influenza A/H1N1 v infection but not confirmed. Regard as probable case, awaiting confirmation	Communicate result only if significant delay likely before confirmatory assay result available. Further testing locally
4	Positive	Negative			Compatible with Swine-lineage Influenza A/H1N1 v infection but not confirmed. Regard as probable case, awaiting confirmation	Communicate result. Further local testing Send sample to Cfl
5	Positive	Negative	Positive	Footnote1	Influenza A virus PCR POSITIVE consistent with Influenza A virus. Further typing tests to follow to confirm whether swine-lineage or human seasonal type. Possible case	Communicate result. Repeat tests locally Send sample to Cfl Urgently
6	Positive	Negative	Negative	Footnote 2	Influenza A virus PCR POSITIVE compatible with Swine lineage Influenza A/H1N1 v but not confirmed. Probable case. Further report to follow	Communicate result. Repeat local tests and consider running Real-time Influenza Quadriplex assay – see VSOP25 – Real-Time Quadriplex PCR for the detection of Influenza or similar generic influenza A matrix assay nucleic acid amplification test. Send sample to Cfl Urgently

¹ Arrange urgent transport of sample to Cfl for confirmation, particularly to exclude mixed infection. Consider possibility of false results in one or other assay and repeat, interpret in light of repeat test results.

². Arrange urgent transport of sample to Cfl for confirmation. Consider possibility of false results in one or other assay and repeat, interpret in light of repeat test results.

* These should be reported as interim results only where N1 testing will be significantly delayed

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This National Standard Method has been developed, reviewed and revised by the Standard Methods Working Group for Virology (http://www.hpa-standardmethods.org.uk/wg_virology.asp). The contributions of many individuals in clinical bacteriology laboratories and specialist organisations who have provided information and comment during the development of this document, and final editing by the Medical Editor are acknowledged.

The National Standard Methods are issued by Standards Unit, Department for Evaluations, Standards and Training, Centre for Infections, Health Protection Agency London.

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REFERENCES

1. Department of Health NHS Executive: The Caldicott Committee. Report on the review of patient-identifiable information. London. December 1997.
2. Advice on working with influenza viruses. <http://www.hse.gov.uk/biosafety/diseases/pandflu.htm>. p. 1-6.