



Public Health
England

Protecting and improving the nation's health

National Infection Service Laboratories - Reference Colindale

Virus Reference Department User Manual

Version 14, August 2018, Q-Pulse VW0405

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-leading science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health and Social Care, and a distinct delivery organisation with operational autonomy. We provide government, local government, the NHS, Parliament, industry and the public with evidence-based professional, scientific and delivery expertise and support.

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Foreword

The PHE National Infection Service's Virus Reference Department (VRD) is a national and international reference centre for a wide range of virus infections. We receive clinical samples and viral isolates from public health departments, National Health Service and commercial laboratories across the UK and internationally for specialist testing, virus characterisation and susceptibility testing. During 2017/18 more than 200,000 tests were performed on over 90,000 reference specimens in VRD which reflects the value of VRD services to clinicians, microbiologists, consultants in communicable disease control, and PHE Surveillance colleagues.

The department is made up of eight units, including the Respiratory Virus Unit, which includes the UK WHO National Influenza Laboratory; the Enteric Virus Unit; Polio Reference Services, which includes the National Polio Laboratory; the Immunisation and Diagnosis Unit, which includes the WHO Global specialised Measles and Rubella Reference Laboratory; the Antiviral Unit, which includes a WHO Global Specialised HIV Drug Resistance Laboratory; and the Clinical Services Unit, which is listed as a WHO Pre-qualification evaluation laboratory. VRD also houses the Blood Borne Virus Unit with NHS Blood and Transplant, providing reference services for hepatitis viruses and other risks to blood supply, and the Human Papillomavirus Unit (HPV Unit) which carries out surveillance and vaccine studies. The department has links with the High Containment Microbiology (HCM) department, which houses a containment level 4 (CL4) laboratory. Members of VRD staff sit on a number of national and international panels and provide advice to the WHO, FSA, Dept. of Health, European Union and ECDC, and provide assistance and advice in national and international outbreak investigations.

The main focus of the laboratory's work is to provide reference and specialist diagnostic services for the United Kingdom. The expertise developed through the provision of this reference service supports a substantial applied research and development programme. We also provide support for outbreak investigations in the UK and internationally. VRD was involved in the development and evaluation of oral fluid and dried blood spot testing for HIV, hepatitis viruses, measles, mumps and rubella. The resultant national diagnostic service offered to primary care plays an important role in monitoring vaccine programmes and infection in hard-to-reach groups. The WHO Measles and Rubella laboratory has established two web-reportable sequence databases which are used by the WHO laboratory network. The WHO National Influenza Laboratory has been involved in establishing the national influenza diagnostic network and has played a key role in the investigation of avian influenza outbreaks and influenza pandemics, including the development of diagnostic tests and vaccine evaluation. Currently the focus is on responding to emerging novel viruses, such as MERS and Zika, and in a wide-ranging programme assessing the value of whole genome sequencing for public health virology.

Disclaimer

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Amendment history

Version No.	Date	Sections Affected	Pages Affected
9	December 2015	Services available, key personnel, unit information, contact details	All
10	September 2016	Services available, key factors affecting tests, key personnel, unit information, contact details	All
11	January 2017	Establishment of service agreement, request forms and specimen transportation, key factors affecting tests, unit information, contact details	5, 8-9, 10-11, 30-36
12	June 2017	Link added to PHE T&Cs. Changes to poliovirus testing arrangements	5 22
13	August 2017	Sample volume requirements for Chlamydia and Neisseria PCR. Enteric virus turnaround times. Personnel details	13, 21,30
14	August 2018	Key factors affecting tests, services available, Polio Reference Service information, contact details	All

Establishment of Service Agreement

Each request accepted by the laboratory for examination is considered to be an agreement under PHE terms and conditions of business. These may be found on the PHE web site using [this link](#) or by searching www.gov.uk for “PHE terms and conditions”.

Key personnel and contact details

Name	Designation	Email	Telephone
Professor Neil Woodford	Deputy Director of NIS Laboratories	neil.woodford@phe.gov.uk	020 8327 6511
Mr Steve Harbour	Technical Head of Operations, NIS Laboratories - Reference	steve.harbour@phe.gov.uk	020 8327 6432

PHE MS Colindale switchboard: 020 8200 4400

VRD General Office

Telephone: 020 8327 6017 (staffed 8am – 5.30pm Mon-Fri)

Fax: 020 8200 1569

Email: vrqueries@phe.gov.uk

DX address:

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VRD
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Postal Address:

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Public Health England
Virus Reference Department
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How to obtain services

Hours of service

The Department is open from 9am to 5pm, Monday to Friday. Telephone enquiries via the VRD general office are available from 8am to 5.30pm, Monday to Friday. No routine services are available outside these hours. The Department is closed on public holidays.

A 24 hour on-call service for the urgent diagnosis of viral haemorrhagic fevers and smallpox is available. Contact the Colindale Duty Doctor on telephone 020 8200 4400.

Services to the public

VRD does not offer diagnostic services to members of the public except via a registered medical practitioner. Results can only be issued to the requesting physician or medical unit and will not be given to patients directly under any circumstance. We reserve the right to check the authenticity of callers in order to protect the confidentiality of patients' personal data.

There are no clinical facilities at PHE Colindale and we are unable to see patients or give telephone medical advice directly to members of the public.

Specimen submission guidelines

Specimens

All specimens **must** be labelled with the following:

- surname/forename or other unique patient identifier
- date of birth
- sender's sample number
- date of collection of specimen

Printed specimen labels should be used wherever possible. Please note that unlabelled specimens cannot be processed and may be discarded.

Request forms

VRD specific request forms are available from our [web pages](#). Guidelines for the completion of forms may be found on our web pages [here](#).

Users are advised to use these forms for all requests and to complete them with the details below.

Forms **must** match the information on the sample. Any specimens where there is a mismatch between data on the sample and on the request form may be rejected. Forms **must** include the following information:

- tests required
- specimen type and site where appropriate
- hazard group, if known or suspected to contain Hazard Group 3 pathogens (**special arrangements apply for specimens suspected of harbouring hazard group 4 agents – see section on specimen transportation on page 9**).
- date of collection
- sender's sample number
- contact information of requester (vital for urgent requests)

Request Forms should also have:

- date of dispatch
- sex
- relevant clinical information including details of any antiviral therapy
- date of onset
- vaccination history
- NHS number
- reference to any previous VRD reports (please give VRD laboratory number if known)

For investigations of maternal transmission, please identify the linked mother or child.

Please complete the forms in BLACK ink (NOT red or any other colour)

Failure to comply with our specimen submission guidelines may lead to specimen rejection and/or delay of reports.

Forensic and medico-legal specimens

The department has capabilities for testing of medico-legal specimens and certain types of forensic specimens.

All requests for forensic tests must be discussed with the department's deputy director prior to sending the specimen to the laboratory.

Medico-legal and forensic testing is performed under CPA/ISO 15189 and not under ISO 17025. A comment to this effect will be added to all such reports.

Specimen transportation

Specimens sent by post or by courier must be in a sealed container, surrounded by sufficient absorbent packing material to take up any leakage in the event of damage during transit, sealed in a plastic bag and placed in an approved outer container which meets current postal or other transport regulations. Contact the departmental safety manager ([Pamela Litton](#) on 020 8327 6017) or the Virology Specimen Reception manager ([Fiona Clode](#) on 020 8327 7129 or 020 8327 6063) for further information.

Special arrangements are required for the collection and transportation of specimens involving suspected hazard group 4 agents – contact HCM on 020 8327 6437 or 0208 327 6222 for further details.

PHE follows the [Guidance on regulations for the transport of infectious substances 2013-2014](#) (external link), published by the WHO. Specimens sent to VRD laboratories must meet the criteria in these guidelines. Samples which are not packaged appropriately may not be processed.

Arrangements must be made by referring laboratories to ensure that time and temperature requirements (detailed under “Key factors affecting tests”, below) for sample transportation are maintained. Failure to achieve this may compromise sample integrity and the validity of test results. Samples which do not meet the sample acceptance criteria may not be processed.

Samples which are dispatched at ambient temperature (10°C – 25°C) must have a transit time of no more than 72 hours. If the date of receipt is greater than 72 hours from the date of dispatch, the referring laboratory will be informed and the specimens may not be processed.

Please do not to include confidential letters within specimen boxes which are not related to the specimens. These should be sent separately and should be clearly marked for the attention of the addressee only.

Key factors affecting tests

Serology tests:

Samples which are highly haemolysed, hyperlipaemic or which contain microbial contamination should not be sent. Heat inactivated samples may give rise to erroneous results in a number of assays and should not be sent – please contact the relevant unit prior to sending the specimen if no other sample is available.

Serum or plasma samples should be stored at 2-8°C for no longer than 7 days – if stored for a longer period of time, they should be frozen at -20°C or lower.

Repeated freeze-thaw cycles should be avoided, as this may degrade the analyte sought and cause inaccurate quantitation or false negative results. If sending samples at ambient temperature, transit time must be less than 72 hours. Please note that while post-mortem samples may be accepted, only a limited number of tests available from VRD laboratories have been evaluated for use with samples from cadavers.

Certain assays (eg polyomavirus serology assays, avian Influenza antibody testing) require serum only – plasma samples are not suitable. Specific requirements are listed from page 13 onwards. When sending paired sera, please ensure samples are taken at least 14 days apart.

Molecular tests:

EDTA plasma is preferable to serum, as degradation of nucleic acid can occur in serum/ clotted samples, which may result in under-reporting of viral load. Serum or plasma should be separated by centrifugation within four hours of collection.

Samples should be sent as soon as possible, or frozen at -20°C or lower.

Repeated freeze-thaw cycles (>3x) may result in under-quantification and should be avoided. Samples which are highly haemolysed, hyperlipaemic or which contain gross microbial contamination should not be sent; where this is unavoidable (e.g. haemolysed samples from post-mortem specimens) the laboratory should be contacted in advance for advice. Do not send dry swabs, charcoal swabs, swabs in bacterial transport gel or swabs with wooden shafts, as all are unsuitable for molecular testing. Heparinised samples, or samples from patients who have received heparin, may give erroneous results and must not be sent – please contact laboratory for advice.

If the original specimen is not available, cDNA may be sent as an alternative – please contact the relevant unit prior to sending specimen. Details of the extraction and cDNA generation method used must be provided in such cases. Please note that unprotected RNA samples will degrade rapidly and are not suitable.

Details of any antiviral therapy should be given wherever possible.

Whole (unseparated) blood samples:

Certain tests (e.g. HIV and HTLV proviral DNA) require whole unseparated blood collected on EDTA. Samples should be sent to the laboratory as soon as possible after collection. Where possible, whole blood samples should not be sent over a weekend. Samples over three days old may not be suitable for testing.

Samples for poliovirus testing:

Faecal samples should be unadulterated/unprocessed. Two samples collected 24 to 48 hours apart are required, with a minimum weight of 2g (preferably 8-10g). Samples should reach the reference laboratory within 3 days of collection; cooled or dry ice shipment is recommended, but is not essential.

Samples for electron microscopy:

Swabs in liquid medium are not recommended for electron microscopy examination of skin lesions. Suitable specimens are either smears of vesicle fluid dried onto a microscope slide, a piece of crust, scabs, or a biopsy or curettage of the lesion placed in a dry sterile container. Biopsy specimens are preferable for suspected orf as virions often remain cell-associated.

Tissue samples:

Tissue samples received for PCR testing should be received unhomogenised and frozen (or fixed). Samples received at room temperature may give rise to unreliable results, particularly for RNA viruses. Note tissue samples that require PCR for parvovirus B19, measles, mumps or rubella testing will require additional processing time to that stated for other specimen types.

CSF, oral fluid, urine and other samples:

Please contact the relevant unit prior to sending these specimens, as the assays used may not have been validated for these sample types.

Samples for antiviral resistance testing:

Tissue culture isolates are the preferred specimens for HSV and Influenza antiviral resistance testing. Swabs in virus transport medium (VTM) will be accepted; a fresh swab in VTM sent as soon as possible after collection will increase the likelihood of successful virus isolation / culture, however successful isolation cannot be guaranteed.

For HIV genotyping/resistance testing, plasma samples with viral loads of greater than 500 copies/ml are required. For HCV DAA resistance testing, viral loads of greater than 1000 IU/ml are required. Details of antiviral therapy, genotype/subtype and viral load should be given wherever possible.

Samples for influenza strain typing

Nose and/or throat swabs in VTM are the preferred specimens, and fluid from respiratory secretions or tissue culture isolates if available will be accepted. Virus

isolation (in tissue culture) is required prior to influenza virus strain typing by haemagglutination inhibition (HAI) and phenotypic antiviral susceptibility testing. Respiratory samples sent as soon as possible after collection will increase the likelihood of successful virus isolation, however successful recovery of virus in culture cannot be guaranteed.

Samples for urgent measles testing

The Virus Reference Department no longer offers urgent measles testing. Please contact your local public health laboratory for details on where the service is offered and the sample types needed for testing. Any samples collected and sent for urgent testing should be in addition to routine samples that are required for testing on all suspected cases of measles. These samples should be sent directly to VRD.

Services available

The department undertakes tests for the infections listed on the following pages. Key factors affecting individual tests are noted against the relevant test, including minimum sample volumes where relevant.

Turnaround times are from day of receipt to issue of reports in calendar days. The times shown are the typical turnaround times achieved by the laboratory, but may be longer or shorter depending on the availability of staff and the complexity of the investigation. VRD staff are committed to the fastest possible issue of reports, consistent with accuracy, on the specimens they examine. Turnaround times may vary during seasonal outbreaks; testing may be conducted more frequently during epidemic seasons.

Requests for additional tests: time limits and specimen retention

If additional laboratory testing is required on a sample previously submitted to VRD, please contact the relevant unit in the first instance. Original specimens are normally retained for at least one month (up to several years in the case of certain specimens) but further testing may not be possible due to sample volume constraints, specimen viability or other factors. The unit will be able to advise on the feasibility of using the original specimen for analysis. All requests for additional testing should be accompanied by a written or faxed request form.

A–Z list of tests available

Investigation	Sample required	Target turnaround time	Test schedule	Contact unit
Adenoviruses (enteric)				
PCR	Faeces (<5 days post-onset)	Contact laboratory	Contact laboratory	CSU
Adenoviruses (respiratory)				
Virus detection by PCR / sequencing	Fluid from respiratory secretions, nose and throat swabs, tissue culture fluid	Contact laboratory	Contact laboratory	RVU
Astrovirus				
RT-PCR	Faeces (<5 days post-onset)	Contact laboratory	Contact laboratory	CSU
<i>Chlamydia trachomatis</i>				
<i>C.trachomatis</i> /LGV multiplex PCR	Confirmed <i>C.trachomatis</i> positive clinical specimen: minimum of 500µl residual NAAT swab transport medium, or a fresh dry swab	6 days	Contact laboratory	CSU
Coronavirus				
Virus detection by PCR / sequencing	Fluid from respiratory secretions, nose and throat swabs	Contact laboratory	Contact laboratory	RVU
Coronavirus (SARS)				
Contact laboratory prior to collection of samples				RVU
Coronavirus (MERS-CoV)				
Contact laboratory prior to collection of samples				RVU

Investigation	Sample required	Target turnaround time	Test schedule	Contact unit
Enteroviruses				
RT-PCR (by prior arrangement only)	Faeces, CSF, throat swab, respiratory tract secretions. Other samples by arrangement. Minimum volume: 200µl	Contact laboratory	Faeces: clinical samples tested weekly. For other samples, contact laboratory	EVU
Typing of referred positive samples	Faeces, CSF, throat swab, respiratory tract secretions. Other samples by arrangement. Minimum volume: 200µl	Contact laboratory	Contact laboratory	EVU
Hepatitis A virus (HAV)				
RNA	Serum or plasma (300µl)	14 days	Contact laboratory	BBVU
Genotyping /phylogenetics	Serum or plasma (300µl)	14 days	Contact laboratory	BBVU
Anti-HAV IgG / IgM	Serum or plasma (200µl)	8 days	2-3 times weekly	CSU

Investigation	Sample required	Target turnaround time	Test schedule	Contact unit
Hepatitis B virus (HBV)				
HBsAg detection	Serum or plasma (300µl)	8 days	2-3 times weekly	CSU
	Dried blood spots Oral fluid	Contact lab Contact lab	Contact lab Contact lab	BBVU BBVU
HBsAg quantification	Serum or plasma (300µl)	8 days	2-3 times weekly	CSU
HBsAg neutralisation	Serum or plasma (500µl)	15 days	Thursday	CSU
HBeAg	Serum or plasma (300µl)	8 days	2-3 times weekly	CSU
Anti-HBc	Serum or plasma (300µl)	8 days	2-3 times weekly	CSU
	Dried blood spots Oral fluid	Contact lab Contact lab	Contact lab Contact lab	BBVU BBVU
Anti-HBc IgM	Serum or plasma (300µl)	8 days	2-3 times weekly	CSU
Anti-HBs	Serum or plasma (200µl)	8 days	2-3 times weekly	CSU
Anti-HBe	Serum or plasma (300µl)	8 days	2-3 times weekly	CSU
DNA viral load	EDTA plasma (300µl)	8 days	2-3 times weekly	CSU
Pre-core / BCP mutation screen	EDTA plasma (300µl)	28 days	Monday	BBVU
Surface mutation screen	EDTA plasma (300µl)	28 days	Monday	BBVU
Antiviral resistance	EDTA plasma (300µl)	28 days	Monday	BBVU
Genotyping /phylogenetics	EDTA plasma (300µl)	28 days	Monday	BBVU

Investigation	Sample required	Target turnaround time	Test schedule	Contact unit
Hepatitis C virus (HCV)				
Antibody confirmation and viral load	EDTA plasma (400µl)	8 days	2-3 times weekly	CSU
Antibody confirmation (dried blood spots and oral fluid samples)	Dried blood spots Oral fluid	By special arrangement only. Contact lab for details.	Contact laboratory	BBVU
RNA viral load	EDTA plasma (300µl)	8 days	2-3 times weekly	CSU
Enhanced sensitivity viral load (sensitivity >15 IU/ml). Please contact lab prior to sample referral.	EDTA plasma (>2ml)	Contact laboratory	Contact laboratory	CSU
Qualitative RNA detection	Dried blood spots	Contact lab	Contact lab	BBVU
Genotyping (NS5B sequencing)	EDTA plasma (300µl)	10 days	Wed, Fri	CSU
	Dried blood spots	Contact lab	Contact lab	BBVU
Phylogenetics	EDTA plasma (300µl)	8 days	Contact lab	BBVU
HCV Q80K testing	EDTA plasma	21 days	Contact lab	AVU
HCV DAA genotypic resistance testing	EDTA plasma (>1ml)	Contact lab	Contact lab	AVU
Hepatitis Delta virus (HDV)				
Anti-HDV IgG	Serum or plasma (200µl)	15 days	Weekly	CSU
Anti-HDV IgM	Serum or plasma (200µl)	Contact laboratory	Contact laboratory	CSU
RNA	EDTA plasma (300µl)	Contact laboratory	Contact laboratory	BBVU
Hepatitis E virus (HEV)				
Anti-HEV IgG	Serum or plasma (100µl)	8 days	3 times weekly	CSU
Anti-HEV IgM	Serum or plasma (100µl)	8 days	3 times weekly	CSU
RNA	EDTA plasma (300µl)	14 days	Mon, Thurs	BBVU
Genotyping /phylogenetics	EDTA plasma (300µl)	Contact laboratory	Contact laboratory	BBVU

Investigation	Sample required	Target turnaround time	Test schedule	Contact unit
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Herpes simplex virus (HSV 1 and 2)

Phenotypic drug resistance	Tissue culture isolate	21 days		AVU
	Swab in VTM. (NB: please see note regarding swabs on page 11)	28 days	Contact laboratory	AVU
Genotypic drug resistance	Serum, plasma, CSF (200µl), swab	14 days	Contact lab	AVU
Intrathecal antibody testing	Paired serum and CSF (100 µl each)	Contact laboratory	Contact laboratory	IDU

Herpes B virus

Contact HCM prior to collection of specimens

HIV-1 and HIV-2

HIV 1 / HIV-2 antibody screen / confirmation / typing	Serum or plasma (500µl)	8 days	Tue, Wed, Thurs	CSU
	Dried blood spots	Contact lab	Contact lab	CSU
	Oral fluid	Contact lab	Contact lab	CSU
HIV-1 proviral DNA	Unseparated blood on EDTA	8 days	2-3 times weekly	CSU
HIV-1 p24 antigen with neutralisation	Serum or plasma (500µl)	8 days	Mon, Thur	CSU
HIV-1 incidence testing (avidity)	Serum or plasma (200µl)	8 days	2-3 times weekly	CSU
HIV-1 genotypic resistance	EDTA plasma (>1ml)	21 days	Contact lab	AVU
HIV-1 proviral tropism testing	Unseparated blood on EDTA	21 days	Contact lab	AVU
Detection of minority drug resistance mutants	EDTA plasma (>1ml)	Contact lab	Contact lab	AVU
HIV-1 sequencing and sequence comparison	EDTA plasma (>1ml)	Contact lab	Contact lab	AVU

Investigation	Sample required	Target turnaround time	Test schedule	Contact unit
HTLV-I/II				
HTLV antibody screen / confirmation / typing	Serum or plasma (300µl)	8 days	Screen: 2-3 times weekly. Confirmation and typing: weekly (Tues)	CSU
HTLV type-specific PCR	Unseparated blood on EDTA	Contact laboratory	Twice per month	CSU
Human herpesvirus 6 (HHV-6)				
Genotyping and confirmation of integration Note: testing performed only on known PCR positive samples	CSF, serum or plasma (150µl), whole blood (500µl)	21 days	Twice per month	IDU
Human herpesvirus 7 (HHV-7)				
PCR	CSF, serum or plasma (150µl), whole blood (500µl)	21 days	Twice per month	IDU
Human herpesvirus 8 (HHV-8)				
Quantitative DNA PCR	Unseparated blood on EDTA. Other specimens by arrangement with laboratory	15 days	Contact laboratory	CSU
Human metapneumovirus				
Virus detection by multiplex PCR	Fluid from respiratory secretions, nose and throat swabs	7 days in season (Nov-Mar)	Daily in season	RVU

Investigation	Sample required	Target turnaround time	Test schedule	Contact unit
Influenza				
Virus detection by multiplex PCR	Fluid from respiratory secretions, nose and throat swabs	7 days in season (Nov-Mar)	Daily in season	RVU
Strain typing HAI	Fluid from respiratory secretions, nose and throat swabs, tissue culture fluid	30 days in season (Nov-Mar)	2-3 runs per week in season	RVU
Antibody response HAI	Paired acute and convalescent sera (minimum 1ml)	Consult laboratory	Consult laboratory	RVU
Phenotypic drug resistance	Fluid from respiratory secretions, nose & throat swabs in VTM, tissue culture fluid	30 days in season (Nov-Mar)	Consult laboratory	RVU
Genotypic drug resistance by pyrosequencing	Respiratory sample in lysis buffer. Fluid from respiratory secretions, nose and throat swabs	3 working days in season (Nov-Mar)	Consult laboratory	RVU
Genotypic drug resistance by gene sequencing	Respiratory sample in lysis buffer. Fluid from respiratory secretions, nose and throat swabs	30 days	Consult laboratory	RVU
Influenza (avian)				
Confirmation of regional lab H5, H7 or H9 virus detection	Respiratory sample in lysis buffer, fluid from respiratory secretions, nose and throat swabs, tissue culture fluid	24 hours	Consult laboratory	RVU
Antibody response	Paired sera (minimum 1ml)	Consult laboratory	Consult laboratory	RVU
Lymphocytic choriomeningitis virus (LCMV)				

Contact HCM prior to collection of specimens

Investigation	Sample required	Target turnaround time	Test schedule	Contact unit
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Measles

IgM serology for recent infection	Serum or plasma (100µl), oral fluid (Oracol)	4 days	Twice weekly	CSU
Re urgent measles testing: please see note on p12				
IgG antibody status	Serum or plasma (100µl)	10 days	Twice weekly	CSU
Intrathecal antibody testing	Paired serum and CSF (100µl each)	Contact lab	Contact lab	IDU
PCR	Oral fluid (Oracol), throat swabs, NPA, CSF (150µl), urine, tissue	10 days (Tissue: contact lab)	Twice weekly	CSU
Plaque reduction neutralisation assay	Serum or plasma (200µl following consultation with laboratory)	Contact laboratory	Contact laboratory	IDU

MERS-CoV

Refer to coronavirus section on page 14.	RVU
Contact laboratory prior to collection of specimens.	

Molluscum contagiosum

Electron microscopy	Suitable specimens are either smears of vesicle fluid dried onto a microscope slide, or a piece of crust or biopsy of a lesion placed in a dry sterile container. Please note swabs of skin lesions in liquid media are not recommended for electron microscopy.	4 days	As required	HPHCU
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Investigation	Sample required	Target turnaround time	Test schedule	Contact unit
Mumps				
IgM serology for recent infection	Serum or plasma (100µl) Oral fluid (Oracol)	10 days	Twice weekly	CSU
IgG antibody status	Serum or plasma (100µl)	10 days	Twice weekly	CSU
PCR	Oral fluid (Oracol), throat swabs, NPA, urine or CSF (150µl)	10 days	Twice weekly	CSU
Noroviruses				
Diagnostic RT-PCR (by prior arrangement only)	Faeces (<5 days post-onset)	Contact laboratory	Clinical samples: tested weekly	EVU
Genotyping of referred positive samples	Faeces (<5 days post-onset)	Contact laboratory	Contact laboratory	EVU
Environmental investigations	Contact laboratory	Contact laboratory	Contact laboratory	EVU
Orf				
Electron microscopy	Biopsy specimens are preferable for suspected orf. Suitable alternative specimens are either smears of vesicle fluid dried onto a microscope slide, or a piece of crust or biopsy of the lesion placed in a dry sterile container. Please note swabs of skin lesions in liquid media are not recommended for electron microscopy.	4 days	As required	HPHCU

Investigation	Sample required	Target turnaround time	Test schedule	Contact unit
Parainfluenza				
Virus detection by PCR / sequencing	Fluid from respiratory secretions, nose and throat swabs	Contact laboratory	Contact laboratory	RVU
Parechovirus				
Diagnostic RT-PCR	Faeces, CSF, respiratory secretions / swab, serum; other samples by arrangement. Minimum volume 200µl	Contact laboratory	Contact laboratory	EVU
Typing	Faeces, CSF, respiratory secretions / swab, serum; other samples by arrangement. Minimum volume 200µl	Contact laboratory	Contact laboratory	EVU
Parvovirus B19				
Serology (IgG/ IgM)	Serum or plasma (200µl)	10 days	Twice weekly	CSU
PCR / genotyping	Serum or plasma (150µl), amniotic fluid (150µl), placenta, foetal tissue (frozen)	10 days (Tissue: contact lab)	Twice weekly	IDU
Polioviruses				
Virus culture / RT-PCR / genotyping	Unprocessed faeces (required for all AFP cases): two samples collected 24-48h apart, min.2g (8-10g preferred), respiratory tract specimens, CSF	Contact laboratory	Contact laboratory	PRS
Poliovirus serology	Serum with date of collection; please refer to "Poliomyelitis: Indications for serological testing" at www.gov.uk			PRS

Investigation	Sample required	Target turnaround time	Test schedule	Contact unit
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Polyomavirus JC

Serology	CSF, serum (50µl)	10 days	Weekly	IDU
PCR	CSF, urine (150µl), tissue, serum, plasma, whole blood	10 days	Weekly	IDU
Intrathecal antibody testing	Paired serum and CSF (100µl each)	Contact laboratory	Contact laboratory	IDU

Poxviruses

(other than orf or molluscum contagiosum – see separate entries on pages 21 and 22)

Contact HCM prior to collection of specimens**Rabies exposure**

Exposure advice only - contact rabies clerk on 020 8327 6204

Respiratory syncytial virus (RSV)

Virus detection by multiplex PCR	Fluid from respiratory secretions, nose and throat swabs	7 days in season (Nov-Mar)	Daily in season	RVU
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Rhinovirus

Virus detection by PCR	Fluid from respiratory secretions, nose and throat swabs	Contact laboratory	Contact laboratory	RVU
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Rubella

IgG / IgM serology for recent infection	Serum or plasma (50µl), oral fluid (Oracol)	10 days	Twice weekly	CSU
IgG antibody status	Serum or plasma (100µl)	10 days	Twice weekly	CSU
PCR and genotyping	Oral fluid (Oracol), throat swabs, NPA, urine, CSF (150µl), amniotic fluid (150µl), placenta, foetal tissue (frozen)	10 days (Tissue: contact lab)	Weekly	IDU

Investigation	Sample required	Target turnaround time	Test schedule	Contact unit
Rotavirus				
Diagnostic RT-PCR (by prior arrangement only)	Faeces (<5 days post-onset); other samples by arrangement. Minimum volume 200µl	20 days	Clinical samples: weekly	EVU
Genotyping of referred positive samples	Faeces; other samples by prior arrangement. Minimum volume 200µl	Contact laboratory	Contact laboratory	EVU
Sapovirus				
Diagnostic RT-PCR (by prior arrangement only)	Faeces (<5 days post-onset)	Contact laboratory	Contact laboratory	EVU
SARS				
Refer to coronavirus section on page 14. Contact laboratory prior to collection of specimens				RVU
Treponema (syphilis)				
<i>T. pallidum</i> serology	Serum or plasma (300µl, free of lysed blood)	6 days	Contact lab	CSU
	CSF (300µl, free of lysed blood)	8 days	Weekly	CSU
<i>T. pallidum</i> / <i>Haemophilus ducreyi</i> /Herpes Simplex Virus (HSV) complex (Genital ulcer disease) - PCR	Fresh dry swab or swab in viral transport medium is optimal, taken from genital or oral ulcer	6 days	Contact lab	CSU
Unknown haemadsorbing agents				
	Tissue culture fluid	Contact laboratory	Contact laboratory	RVU

Investigation	Sample required	Target turnaround time	Test schedule	Contact unit
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Varicella-zoster virus (VZV)

IgG serology	Serum or plasma (100µl)	21 days	Fortnightly	IDU
IgM serology	Contact lab	Contact lab	Contact lab	IDU
Intrathecal antibody testing	Paired serum and CSF (100µl each)	Contact laboratory	Contact laboratory	IDU
PCR / genotyping	Vesicular fluid (200µl)	21 days	Twice per month	IDU

Viral haemorrhagic fevers

Special arrangements are required for the collection and transport of specimens potentially harbouring these agents. Contact HCM for information on sample type and method of transportation prior to specimen collection.

To discuss any patient with undiagnosed fever following recent travel abroad the Infectious Diseases, Microbiology or Virology doctor should call the Imported Fever Service on 0844 77 88 990

Reports

Reports will be delivered electronically via E-lab, or will be printed and delivered by post if the referring laboratory is not registered to E-lab. For details on how to register for E-lab and further information, please email

LimsHelpdesk@phe.gov.uk

Please note reports will only be sent to the requestor named on the request form.

Policy on faxing and emailing reports containing patients' data

The following guidelines have been prepared having taken into account the code of practice on reporting patients' results by fax prepared by the Department of Health and Caldicott recommendations.

1. It is PHE Reference Microbiology policy that reports containing patients' data should **not** be sent by fax or email.
2. Emails cannot be relied on to guarantee security of patients' data because they can be intercepted by a third party en route.
3. In **exceptional** circumstances it may be necessary to send a result by fax but not by email. In this case, the following conditions must be adhered to after telephone discussion with the Laboratory. Refer also to "PHE Reference Microbiology - recognition of Caldicott recommendations" on page 26 of this manual.

The report must be sent to a "safe-haven" fax machine. This means that, if the location is in general use, consideration must be given to ensuring that unauthorised personnel are unable to read reports, accidentally or otherwise. Also, the room housing the fax machine must be kept in a secure location which is locked if it is likely to be unattended at the time the fax is sent.

Assurance must be sought from the intended recipient of the faxed report, preferably in writing, that the receiving fax machine is a "safe-haven".

Measures must be taken to minimise the risk of mis-dialling, either by double-checking numbers or having frequently used numbers available on the fax machine's memory dial facility.

Confirmation must always be sought from the intended recipient that the fax is expected and has been received.

Quality assurance in VRD

The Virus Reference Department participates in numerous EQA schemes, including those run by the UK National External Quality Assessment Service (NEQAS), the World Health Organisation (WHO), Centres for Disease Control, Atlanta (CDC), the European Influenza Surveillance Network (EISN), Quality Control for Molecular Diagnostics (QCMD), UK Influenza Laboratory Network and the UK Genotypic Resistance Network. Details of participation in specific schemes are available on request.

The quality of our systems is also checked by our IQA schemes, which requires selection of referred samples for “blinded” testing at a later date. After processing, the results for IQA samples are unblinded and are assessed against the results originally reported to the sending laboratory. Any discrepancies are fully investigated as to their root cause before remedial action is implemented. Results of our EQA and IQA performance are discussed at Quarterly Management Review meetings, and also at unit meetings, as appropriate.

Complaints

If there is a problem, or you are not satisfied with the service you have received, in the first instance contact the appropriate Unit Head. Contact details are given on the following pages against each unit, and in summary at the end of the user manual.

Otherwise contact:

Deputy Director of Reference Microbiology:

Professor Neil Woodford (020 8327 6511),

email neil.woodford@phe.gov.uk

or

Technical Head of Operations, Reference Microbiology:

Mr Steve Harbour (020 8327 6432),

email steve.harbour@phe.gov.uk

Our endeavour is to be responsive to the changing needs of all users of our services. We welcome comments on how we can improve the provision of these services. Please contact the department if you have any queries.

PHE Reference Microbiology - recognition of Caldicott recommendations

The recommendations of the Caldicott Report (1997) and the subsequent Information Governance Review (2013) have been adopted by Public Health England and by the National Health Service as a whole. These recommendations relate to the security of patient identifying data (PID) and the uses to which they are put. PHE Reference Microbiology observes Caldicott guidance in handling PID and has appointed its own Caldicott Guardian. He advises the Director of the Virus Reference Department and others on confidentiality issues and is responsible for monitoring the physical security of PID in all parts of the Colindale site. This also applies to the transfer of results of investigations to and from the site whether by mail services, telephone or fax. The value of 'safe haven' arrangements or other means of the sender and receiver of information identifying themselves to each other before data is transferred is emphasised. (see policy on faxing and e-mailing reports containing patients' data on page 24 of this manual).

PHE Reference Microbiology is anxious to audit the security of its PID in collaboration with its customers. Customers are invited to review our arrangements in conjunction with individual laboratory directors and/or the Reference Microbiology Caldicott Guardian. Customers are also asked to draw to the Reference Microbiology Caldicott Guardian's attention any instances where PID security has been threatened or has broken down. Uses that PID are put to outside clinical diagnostic services generally allow patient identifiers to have been removed beforehand, and when PID is used for research purposes the proposals are considered first by the PHE Research Ethics Committee. All enquiries about the security and use of PID at PHE Reference Microbiology Colindale should be addressed to the Associate Caldicott Guardian, Dr Kevin Dunbar (kevin.dunbar@phe.gov.uk)

Compliance with the Human Tissue Act: submitting tissue samples from deceased people

PHE Colindale is licensed by the Human Tissue Authority (licence number 12459) to store tissues from deceased people for scheduled purposes. Post mortem samples are submitted by coroners or pathologists for examination to help them determine the cause of death.

Obtaining consent to remove, store and use human tissues for a scheduled purpose is one of the underlying principles of the Human Tissue Act. Reference Microbiology Colindale receives post-mortem samples from coroners' post-mortems or from NHS establishments across the UK and therefore we are performing the examination under the authority of the coroner. Unless consent has been obtained or the coroner has requested that samples are retained for further testing, samples are disposed of within three months of the initial test being performed.

When tissue samples from deceased people are received at Reference Microbiology Colindale they are retained securely and confidentiality is maintained in compliance with Caldicott principles as are all samples received at this centre. It is normal practice for tissue samples from the deceased to be disposed of in the same way that all other clinical samples we receive are disposed of. However, we will adhere to any specific requirements regarding disposal or returning tissue samples if requested by the sending coroner or pathologist.

Unit information

Antiviral Unit (AVU)

Acting Head of Unit: Dr Tamyo Mbisa (Tel: 020 8327 6099)

The Antiviral Unit houses a WHO Global Specialised HIV Drug Resistance Laboratory.

The unit provides reference services for genotypic resistance testing of HIV and HCV (including minority mutant detection), analysis of HIV transmission events for public health-related investigations, HIV subtyping by sequencing, and HSV antiviral resistance testing.

Other reference and training activities include organisation of UK EQA for HIV resistance testing, provision of training in laboratory and clinical aspects of HIV, HCV and HSV resistance testing, especially implementation of new assays, and leading the UK HIV genotypic resistance working group.

Research activities include development and roll-out of novel genotypic assays for detection of drug resistance in HIV, HCV and HSV (including NGS technologies), development and application of phenotypic assays for investigation of HIV drug resistance, investigation of the role of accessory mutations in levels of HIV drug resistance and viral fitness, and investigation of early events in HIV transmission.

Blood Borne Viruses Unit (BBVU)

Head of Unit: Professor Richard Tedder (Tel: 020 8327 6553)

Deputy Head of Unit: Dr Samreen Ijaz (Tel: 020 8327 6554)

The Blood Borne Virus Unit is engaged in research and development on Hepatitis Viruses and works closely with the Clinical Services Unit (CSU) at PHE Colindale and with the NHS Blood and Transplant Service (NHSBT).

Some of the work of the PHE Blood Borne Virus Unit is around improving blood safety. This is funded by NHSBT and members of the unit work closely with colleagues in the NHSBT/PHE Epidemiology Unit.

The unit provides services for the molecular epidemiology of Hepatitis A, B, C and E transmission incidents and outbreaks, antiviral resistance testing for HBV, anti-HBc avidity testing, screening for HBsAg, pre-core and BCP mutations, sequencing and phylogenetic analysis for Hepatitis A, B, C and E, and real-time HDV RNA and HEV RNA assays.

Surveillance activities include sequencing of acute HAV and HBV cases, and enhanced surveillance programmes for HAV, HBV and HEV. For details on the enhanced surveillance programmes, please contact the unit.

Research activities include epitope mapping of HBsAg variants including vaccine escape mutants, and blood safety studies in collaboration with NHSBT.

Clinical Services Unit (CSU)

Scientific Leads: Dr Gary Murphy (Tel: 020 8327 6935)
 Dr Keith Perry (Tel: 020 8327 6308)

Clinical enquiries:

HIV, HTLV, HSV – Jenny Tosswill (Tel: 020 8327 6274)
Hepatitis – Dr Siew-Lin Ngui (Tel: 020 8327 6555)
HHV-8 – Dr Simon Carne (Tel: 020 8327 6546)

The unit provides diagnostic reference work relating to HIV-1 and HIV-2, Hepatitis viruses A, B, C, D and E, HTLV-I and -II, HHV-8, measles, mumps, rubella, parvovirus B19 and Treponema (syphilis). The laboratory also undertakes molecular confirmatory testing for *C.trachomatis*/LGV. A full list of services provided by the unit is shown in the “Services Available” section beginning on page 12 of this manual. The Laboratory provides high-throughput serological and molecular surveillance services. The Unit is listed as a WHO Pre-qualification evaluation laboratory.

Enteric Viruses Unit (EVU)

Interim Head of Unit: Dr Jake Dunning (Tel: 020 8327 7837)
Senior Biomedical Scientist: Stuart Beard (Tel: 020 8327 6349)

The primary function of the national reference laboratory is to characterise non-polio enteroviruses, rotaviruses and noroviruses, to support national surveillance programmes and investigations of significant outbreaks. EVU can perform detection assays for specific enteric viruses, but only when detection assays are not offered by NHS and regional PHE Public Health Laboratories. EVU characterisation assays are not associated with specific turn-around times.

A comprehensive sequence database of characterised norovirus, sapovirus, astrovirus and rotavirus strains, including geographical and temporal distributions and the genetic diversity of co-circulating strains, has been established in collaboration with the Bioinformatics Unit. EVU collaborates with other PHE departments, NHS and academic institutions in the structured surveillance and study of enteric virus infections and the diseases they cause

High Containment Microbiology (HCM) department

Clinical & Scientific Lead: Dr Robin Gopal (Tel: 020 8327 6437)
Technical Manager: Matthew Jones (Tel: 020 8327 6222)
Electron Microscopist: Dr Matthew Hannah (Tel: 020 8327 6386)

The unit hosts a modern imaging facility to provide electron and confocal microscopy.

The unit provides a diagnostic service for viral haemorrhagic fevers, poxviruses, LCM and herpes B virus.

Please note: special arrangements are required for the collection and transport of specimens potentially harbouring these agents. Contact the laboratory for information on sample type and method of transportation prior to specimen collection

To discuss any patient with undiagnosed fever following recent travel abroad the Infectious Diseases, Microbiology or Virology doctor should call the Imported Fever Service on 0844 77 88 990

Note: If infection with a Hazard Group 4 pathogen is suspected from clinical information or travel history, you must contact this number before sending.

Human Papillomavirus Unit

Acting Head of Unit: Dr Simon Beddows (Tel: 020 8327 6169)

The unit contributes to national sexually transmitted infection surveillance programmes designed to monitor the impact of the HPV vaccines on the UK population. We also undertake studies to understand the immune responses generated following HPV vaccination and those generated during natural infection. The unit does not offer a diagnostic service for HPV infection.

Electron & Confocal Microscopy: We have a modern ultrastructural imaging facility with a 120kV high-contrast, transmission electron microscope and a state-of-the-art laser scanning confocal microscope. The facility provides a diagnostic service to the NHS for orf and molluscum contagiosum viruses using negative stain EM and also supports the research and development activities of PHE scientists. Current topics being addressed within the imaging facility include; capsid protein purification, uptake of recombinant virus particles, morphological variability within strains of pathogenic bacteria, bacteriophage discovery, effects of antiviral drugs on virus maturation and virus envelope protein trafficking.

Immunisation and Diagnosis Unit (IDU)

Head of Unit: Dr Kevin E Brown (Tel: 020 8327 6023)

The unit provides diagnostic and reference services for measles, mumps, rubella, JC polyomavirus, parvovirus B19 (B19V), varicella-zoster virus (VZV), HHV6 and HHV7, and in collaboration with the Immunisation Department is responsible for the enhanced laboratory surveillance for measles, mumps and rubella infection in the UK. The laboratory also offers intrathecal antibody testing for investigation of meningoencephalitis.

The unit is a national and international reference centre for rash associated viral infections and the unit receives clinical samples and virus isolates from PHE, National Health Service and commercial laboratories across the UK and from overseas.

Services provided by the laboratory include reference serum and oral fluid antibody tests for rash illnesses, advice on management of rash outbreaks, investigation of adverse reactions following vaccination, and antigenic characterisation of measles, mumps, rubella and B19 infections.

In collaboration with CSU, the unit carries out oral fluid testing (for both antibody and RNA detection) for measles, mumps and rubella. Testing of samples obtained by this non-invasive method has greatly enhanced measles, mumps and

rubella surveillance in the UK, and has been invaluable in tracking recent changes in measles epidemiology following the drop in MMR vaccine uptake in the UK due to unfounded doubts about vaccine safety.

The unit also provides advice on serological assay development, is involved in the development of near-patient tests, and provides monoclonal antibody generation and immunochemical modifications. For further information on these services, please contact the unit.

The unit is one of three WHO Global Specialized laboratories for Measles and Rubella (the other two are located in the USA and Japan). As such, it is responsible for the following services to laboratories within the global network:

- provision of technical advice and specialised training to regional and national laboratories
- provision of laboratory standards, training materials and quality control panels of sera and viruses
- organisation of periodic proficiency testing for regional laboratories
- evaluation and improvement of diagnostic kits and methods
- maintenance of the Measles and Rubella Virus reference strain bank
- provision of viral sequencing and analysis on request
- administration and maintenance of the two WHO measles and rubella sequence databases (MeaNS and RubeNS, respectively).

Polio Reference Service (PRS)

Head of Service: Professor Maria Zambon (Tel: 020 8327 6810)

The Polio Reference Service (PRS) is the WHO-accredited UK national poliovirus laboratory and undertakes performs analyses to exclude polio virus using methodology specified by WHO as part of the global eradication programme. This includes virus isolation by specific cell culture, application of WHO molecular assays, and detection and quantification of anti-poliovirus neutralising antibodies.

The UK is committed to the Global Polio Eradication Initiative and has to conform to the poliovirus testing requirements set by the WHO Global Action Plan. As such, it is essential that the correct sample types be submitted from all cases of suspected poliomyelitis and any case of acute flaccid paralysis/myelitis; further information can be found in the A-Z list of tests available, or by contacting PRS.

Respiratory Virus Unit (RVU)

Head of Unit: Dr Jake Dunning (interim) (Tel: 020 8327 6014)
Scientific Lead: Dr Joanna Ellis (Tel: 020 8327 7633)

The unit provides antigenic and genetic analysis of influenza isolates, and molecular detection, virus isolation in culture and serology tests for a range of respiratory viruses and investigation of outbreaks of respiratory virus infection. Genetic characterisation of respiratory viruses is undertaken, including whole genome sequencing of influenza viruses. Influenza antiviral susceptibility primary testing is performed as required, with genotypic and phenotypic characterisation of strains.

As a WHO National Influenza Laboratory, the unit undertakes:

- National surveillance of influenza and other respiratory viruses
- Antigenic and genetic characterisation of circulating influenza strains is performed
- Data is provided to WHO as evidence from the UK to guide the annual formulation of the influenza vaccine.
- Surveillance of antiviral susceptibility of influenza viruses derived from community and hospital sources, with monitoring achieved through genotypic and phenotypic analysis.

The unit also contributes virological data (antigenic and genetic) to assist seasonal influenza vaccine effectiveness (VE) estimates, including assessment of the effectiveness of new vaccination programmes.

The work of RVU also involves the development of diagnostic tests for current and emerging respiratory viruses, and vaccine evaluation studies.

The unit is one of three WHO global RSV Reference Laboratories, and as such collaborates with WHO, providing technical support and advice to national laboratories.

The unit is also a WHO MERS CoV Reference Laboratory, providing confirmatory and reference services for MERS CoV.

Contacts

Name	Designation	Email	Telephone
Antiviral Unit (AVU)			
Dr Tamyo Mbisa	Unit Head (acting)	tamyo.mbisa@phe.gov.uk	020 8327 6099
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Jenny Tosswill	Clinical Scientist	jennifer.tosswill@phe.gov.uk	020 8327 6274
Blood-borne Virus Unit (BBVU)			
Prof. Richard Tedder	Unit Head	richard.tedder@phe.gov.uk	020 8327 6553
Dr Siew-Lin Ngui	Clinical Scientist	siewlin.ngui@phe.gov.uk	020 8327 6555
Dr Samreen Ijaz	Clinical Scientist	samreen.ijaz@phe.gov.uk	020 8327 6554
Nigel Wallis	Technical Manager	nigel.wallis@phe.gov.uk	020 8327 7017
Enteric Virus Unit (EVU)			
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HPV Unit			
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Immunisation and Diagnosis Unit (IDU)			
Dr Kevin Brown	Unit Head	kevin.brown@phe.gov.uk	020 8327 6023
Dr Li Jin	Clinical Scientist	li.jin@phe.gov.uk	020 8327 6020
Caroline Motamed	Technical Manager	Caroline.motamed@phe.gov.uk	020 8327 6115
Lenesha Warrenner	Senior BMS	Lenesha.warrenner@phe.gov.uk	020 8327 6254
Polio Reference Service (PRS)			
Prof. Maria Zambon	Head of Service	maria.zambon@phe.gov.uk	020 8327 6810
Dr Robin Gopal	Biocontainment & Biosecurity	robin.gopal@phe.gov.uk	020 8327 6437
Dr Kevin Brown	Consultant Medical Virologist	kevin.brown@phe.gov.uk	020 8327 6023
Dr Jake Dunning	Consultant in Infectious Diseases	jake.dunning@phe.gov.uk	020 8327 6014
Respiratory Virus Unit (RVU)			
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Carol Sadler	Technical Manager	carol.sadler@phe.gov.uk	020 8327 6239
Dr Jake Dunning	Medical Consultant	jake.dunning@phe.gov.uk	020 8327 6014

Name	Designation	Email	Telephone
Clinical Services Unit (CSU)			
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Dr Simon Carne	Clinical Scientist	simon.carne@phe.gov.uk	020 8327 6546
High Containment Microbiology (HCM)			
Dr Robin Gopal	Clinical & Scientific lead	robin.gopal@phe.gov.uk	020 8327 6437
Matthew Jones	Technical Manager	matthew.jones@phe.gov.uk	020 8327 6222
Advice on management of rabies exposure			
	Rabies clerk		020 8327 6204