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# CHESTER AND WIRRAL MICROBIOLOGY SERVICE USER GUIDE

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## **REVISION HISTORY**

REVISION	CHANGE DETAILS	SECTION(S)	PAGE(S)	MADE BY	APPROVED BY	ACTIVE DATE
4.1	Changed Aptima swabs to Roche throughout.			BDB	BDB	24.07.23
4.1	Covid details updated	10	28	BDB	BDB	24.07.23
4.1	New IUCD information added	10	35	BDB	BDB	24.07.23
4.1	C.difficile interpretation updated	13	48	BDB	BDB	24.07.23
4.2	Microbiology advice line updated	2	6	BDB	BDB	27.03.24
4.2	Specimen transport added	Throughout		BDB	BDB	27.03.24
4.2	Added micro duty senior email address	2	6	BDB	BDB	27.03.24
4.2	Removal of in-house CT/NG testing/exelicare requesting	Throughout		BDB	BDB	28.03.24
4.2	Added collection and storage conditions	Throughout		BDB	BDB	28.03.24
4.2	Verify patient ID	7	14	BDB	BDB	28.03.24
4.2	Number CSF samples	7.11	20	BDB	BDB	28.03.24
4.2	Users can request UoM reports	11	47	BDB	BDB	28.03.24
4.2	Changes to examination procedures which could affect interpretation will be notified to users.	11	47	BDB	BDB	28.03.24
4.2	Delayed results	3	7	BDB	BDB	28.03.24
4.3	Changed to new template			BDB	BDB	19.11.24
4.4	Added β-D-Glucan		49	BJE	BDB	30.12.24



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#### 1.0 GENERAL INFORMATION

The Medical Microbiology Service is part of collaboration between Wirral University Teaching Hospital NHS Foundation Trust and Countess of Chester NHS Foundation Trust. The main Microbiology Laboratory is located on the Croft Business Park, Bromborough.

#### The Microbiology Laboratory address is:

Chester and Wirral Microbiology Service 11 Bassendale Road, Bromborough, Wirral. CH62 3QL

Tel 01244 362500

24-hour cover is provided for ALL aspects of infectious diseases

#### On-call service for urgent clinical advice

Consultant in Medical Microbiology

Between 17-00 – 09-00 Monday – Friday

Between 17-00 on Friday and 09-00 on Monday (weekends), please contact the Consultant. Microbiologist on-call via the switchboard of each Trust. Please note that the on-call Consultant Microbiologist should only be contacted in response to requests from the following categories of personnel:

**Consultants** (in exceptional circumstances contact may be made by a registrar <u>if</u> the patient has been discussed with the consultant in the team, but the consultant is unable to make the call himself/herself).

#### **Pharmacists**

Laboratory staff

**General Practitioners** 

#### **Countess of Chester Hospital**

There is a 24-hour onsite service providing Molecular testing for SARS-CoV-2 and Flu in Pathology at Countess of Chester Hospital

Blood Sciences Laboratory Department of Pathology CoCH

Tel: 01244 365595



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## 2.0 KEY CONTACTS AND THEIR TELEPHONE NUMBERS/ EXTENSIONS

Laboratory Results/Enquiries
Monday – Sunday 09-00hrs, - 19-00hrs 01244 362500

**Consultant Staff (Wirral)** 

Dr Kavya Mohandas 0151 482 7694

Dr David Harvey 0151 604 7466

**Specialist Doctor** 

Dr A Abdelrahman 0151 678 5111 Ext 7436

**Clinical Scientist (Wirral)** 

Mrs Sharon Bamber 0151 678 5111 Ext 2847

Dr Elizabeth Thursby 0151 552 1875

Medical Secretaries for <u>clinical</u> enquiries (Wirral)

Monday – Friday: 09-00hrs– 17-00hrs 01244 362500 Option 3

Referrals for Microbiology clinical advice for inpatients should be sent via Cerner, using the ORDER "Refer Microbiology Inpatient."

This service will operate during routine working hours between 9:00 - 4.30pm for inpatients only.

For any inpatient referrals on weekdays between 4.30 pm - 5:00 pm, please call Ext 7875 For outpatients during working hours, please call Ext 7875.

**Consultant Staff (Countess of Chester)** 

Dr Ildiko Kustos 01244 366785

Dr Jeremy Gardner 01244 366788

**Staff Grade Doctor (CoCH)** 

Dr Muna Yousif 01244 363518

Clinical Scientist (CoCH)

Mrs Sarah Wood 01244 364062

**Trainee Clinical Scientist (CoCH)** 

Eleanor Senior 01244 366773

Medical Secretaries for <u>clinical</u> enquiries (Countess of Chester)

Monday – Friday: 09-00hrs – 17-00hrs 01244 366773

**Laboratory Manager** 

Ms N Duggan 01244 362499

**Technical Manager / Deputy Laboratory Manager** 

Claire Greene

Dave Bond 01244 363352



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**Quality Management** 

Mrs Joanne Evans 01244 363352

**Senior Biomedical Scientist Team** 

wuth.microdutysenior@nhs.net



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#### 3.0 MEDICAL MICROBIOLOGY – PRINCIPAL SERVICES

#### 3.1 Clinical Service

The principal diagnostic laboratory is based at The Croft Business Park, Bromborough. Limited molecular testing is also performed at APH and CoCH (refer to **Section 1.0**) Access to consultative and principal diagnostic service outlined below is available on a 24-hour basis.

## 3.2 Diagnostic Service

Chester and Wirral Microbiology Service provides a comprehensive microbiological service in medical bacteriology, mycology, virology, parasitology and serological investigations. Advice on the selection of appropriate diagnostic specimens, their collection and transport is available.

The laboratory is accredited by the United Kingdom Accreditation Service (UKAS) to ISO 15189 for the test repertoire stated on the Schedule of Accreditation, which can be accessed at: 9595 Medical Multiple (ukas.com)



Any tests reported that are not on the UKAS Schedule of Accreditation will have the following report code added.

"Test internally verified awaiting UKAS Accreditation"

**Results of clinical significance** are phoned through to the surgery or relevant. medical staff, irrespective of whether the original request is marked as urgent or routine.

**Delay in results** – if there is going to be a significant delay in the availability of results, the users will be informed.

#### **Antimicrobial Therapy and Clinical Consultation**

When a conclusive microbiological diagnosis has been reached, optimum therapeutic regimens. are reported when necessary. They will be reported as:

- **S Susceptible, standard dosing regimen:** A microorganism is categorised as *Susceptible, standard dosing regimen\**, when there is a high likelihood of therapeutic success using a standard dosing regimen of the agent
- I –Susceptible, increased exposure\*: increasing the dose may improve the chance of treatment success



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 R – Resistant: A microorganism is categorised as Resistant when there is a high likelihood of therapeutic failure even when there is increased exposure\*

\* Exposure is a function of how the mode of administration, dose, dosing interval, infusion time, as well as distribution, metabolism and excretion of the antimicrobial agent will influence the infecting organism at the site of infection.

Ref: Redefining S, I and R 2019 - www.eucast.org

The serum concentration of relatively toxic antimicrobials and those used in critical infections. are monitored.

The following empirical (blind / provisional) prescribing regimens can be found in the Wirral Prescribers' Guide and The Chester Joint Formulary

- (a) For patients with severe sepsis and
- (b) When the microbiological diagnosis is inconclusive

#### 3.3 Teaching and Training

The Department of Medical Microbiology supports scientific and professional training for its staff, as well as the teaching of science students attending local universities and colleges. It is also actively involved in providing work experience placements for BTEC students from local colleges. Placements are also given to students undertaking the Biomedical Science degree course at Liverpool John Moore's University and University of Chester.

#### 3.4 Document Control

All documents used in Microbiology are managed electronically via Q pulse and backed up on Countess of Chester Servers to protect their integrity.

There are policies, procedures and templates specific to Microbiology as well as shared directorate documents.

The department is obliged to follow Trust policy and procedures. To avoid duplication some of these policy and procedure documents are used in place of departmental ones.

The Laboratory is hosted by Wirral University Teaching Hospital NHS Foundation Trust policies and procedures are located on the intranet.



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## 4.0 'URGENT' SPECIMENS FOR MICROBIOLOGICAL INVESTIGATION

Biomedical Scientists (BMSs) are available in the laboratory 24 hours a day, 7 days a week to process any samples that are considered urgent. Between 09-00 and 19-00 the BMS must be contacted in the laboratory on 01244 362500 with the details of the request.

#### 4.1 Out of Hours Service

19-00hrs to 09-00hrs 7 days a week

Requests for urgent specimens to be processed after 19-00hrs should be directed to the out of hours Biomedical Scientist through switchboard at either the Wirral site or Countess of Chester Hospital.

The following are out-of-hours requests that may be made via Biomedical Scientists:-

- Paediatric MSSUs for children <u>under</u> 3 years of age (Microscopy / Culture)
- Material from Sterile Sites e.g. Synovial fluid, Peritoneal fluid (e.g. Ascites) CSF
- Pus from deep seated abscesses (Other pus swabs etc. contact the Consultant Medical Microbiologist)
- Pus
- Specimens from theatre (excluding bone/tissue)

#### 4.2 Taxis

The Department operates a 24/7 service for urgent specimens – see the details above – in the unlikely event that a specimen may not be processed urgently because it has missed the transport run then a taxi may be required to transport the sample to the Laboratory at Bromborough between 17-00hrs and 09-00hrs. Samples must be packaged in a robust container and **no** patient details should be visible on the outer packaging (refer to **Sections 8.4 and 9.1 Packaging and Transport**).



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## 5.0 LABELLING REQUIREMENTS FOR REQUESTS (CERNER, ICE AND HANDWRITTEN FORMS)

Requests communicated to the laboratory are as follows:

- Cerner order labels are attached to the sample (no request form required)
- ICE forms generated by the GP practices.
- Handwritten request forms from wards, clinics, or GPs
- All verbal requests to the laboratory must be accompanied by one of the above requests forms for the sample to be processed.

All Locations within each Trust and GP practice should make requests via the above Order Entry Systems – otherwise results may not be viewable electronically. The sample, request label, or request form should clearly state the following information for unequivocal identification of the patient and specimen:

- Patient name (in full no abbreviations)
- Ward, Clinic, or GP name and number/address
- NHS number
- Date of Birth
- Sex
- Type of specimen
- Date and time specimen taken.

**NB** It is **ESSENTIAL** that the laboratory knows the date on which a specimen is taken: processing delayed specimens can yield unhelpful or frankly misleading results and they may be discarded (e.g., urine samples dated 2 days prior to day of receipt). When patients are given a request form and asked to provide a specimen **they should be asked to ensure that the date on which the specimen was collected is given on the container and the form.** 

- Tests required (specify 'TB' if required)
- Only request 'Miscellaneous Microbiology' if the appropriate investigation is not listed on the screen and state the specific investigation required in the clinical details field.
- Antibiotic treatment (recent, current or intended)
- All relevant clinical details
- History of recent foreign travel, if applicable
- · Risk status, if applicable
- Date of onset and duration of illness, particularly for serology
- Specify anatomical site from which "wound" specimens were taken.
- Key epidemiological information, e.g., for faeces
- Request 'OCP' (ova, cysts and parasites) if appropriate

#### **Cerner Requesting**

CERNER is a paperless system that will not generate a request form.

All CERNER requests should have a status of collected in CERNER before sending to the laboratory. The specimens should be sent with the printed label on the specimen. All of the above details are necessary to include when making a CERNER or Excelicare request.



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If uncertain about the exact test and terminology, please give a detailed clinical history as this can help the Laboratory staff to decide the most appropriate investigation.

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#### 6.0 LABELLING REQUIREMENTS FOR SPECIMENS

- The specimen must be labelled with the patient details as on the request form.
- The specimen must be labelled with the date of collection.
- Please note that unlabelled and mislabelled specimens cannot be processed and will be rejected.

If the laboratory cannot unequivocally identify the sample and match it to a form, then it will be rejected.

The laboratory will inform senders by means of an electronic or printed report when a specimen has been rejected for the above reasons.

In certain circumstances it may be possible to add tests to samples that the laboratory has already received.

The table below indicates how long samples are kept in the laboratory before disposal. Requests for extra tests must be received within the sample storage period and must be accompanied by a request form. Please telephone the laboratory before requesting extra tests to ensure the sample is available and still viable.

Sample	Time Kept
Faeces	1 week after primary culture. Aliquot of C diff toxin positive samples – min 3 months
Respiratory samples	1 week after primary culture
Flu samples	1 week after primary screening
Swabs, fluids and aspirates	1 weeks after primary culture
Urines	1 weeks after primary culture
CSF samples	1 month after collection (? CJD samples) stores securely in -70 <sub>o</sub> C freezer until Reference Laboratory report is received)
Blood cultures	Positive bottles – until all follow up work is finalised.  Negative bottles – discarded after 5 days incubation.
Tissue / bone / cartilage	1 month after primary culture
Stained slides	1 week after primary culture
Postmortem tissue	1 month after culture
Mycology samples for culture	Generally, all samples are processed in KOH



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MRSA/CPE/VRE screening swabs	1 week after PCR/primary culture
Left over serum from first pregnancy booking	-20°C 2 years
Left over serum or plasma (other than transplant-related)	Minimum 2 years -20°C
Left over serum or plasma from transplantation, post transplantation donor/recipient sera	Minimum 11 years at -20°C
Serum from accidental exposures to blood and bodily fluids	Minimum 2 years -20°C
All clots	Minimum 1 week at 4°C
Unprocessed samples (e.g., spares)	Minimum 1 week at 4°C
Human milk and serum from milk donors	Milk -10 years at -80°C Sera – 10 years at -20°C



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## 7.0 STANDARD PROCEDURES FOR THE SAFE COLLECTION OF SPECIMENS

These procedures concern all clinical staff who are qualified to collect diagnostic specimens from patients.

Firstly, check who the patient is before taking the sample, both verbally and using the patient's wristband.

**N.B.** Staff must always follow aseptic techniques when handling blood, body fluids, excretions, or secretions, even when these have not been specified as infectious.

#### **Objectives**

All staff must be aware of the potential physical and infectious hazards, associated with these procedures, and should therefore collect specimens:

- 1) Being mindful of personal safety, without injury or exposure of themselves and of collective safety, without exposing colleagues who are involved with the handling, transport and laboratory investigations of specimens, to physical or infectious hazards.
- 2) Staff collecting specimens must take care to prevent contaminating themselves, their environment, the external surfaces of the specimen containers, or the accompanying test request forms. If gross contamination of the hands with blood, faeces or other biological fluids is anticipated, then gloves should be worn. Hands should always be washed after taking specimens. If splashing into the eyes or on to mucous membranes is anticipated goggles should be worn.
- 3) In addition, specimens should be collected aseptically, without allowing contamination by extraneous and, therefore, irrelevant micro-organisms. Contaminated specimens can adversely affect the validity of many laboratory results. For example, the microbiological investigation of contaminated blood or other materials from sites, which are normally sterile, can commit patients to unwarranted courses of expensive and potentially toxic treatment.

#### Before you start

- 1) Ensure that the lighting conditions are adequate.
- 2) Select the correct specimen container (s), appropriate for the type of specimen, and keep the container close to the site from which the specimen is to be obtained.
- Complete, legibly and fully, all section of the label on the specimen container and, check the details on the computer-generated request form are correct or, where used, the test request forms.
- 4) If you suspect, or are aware of, an infection with a Hazard Group 3 pathogen (example of relatively common Hazard Group 3 pathogens are Hepatitis B virus, Human



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Immunodeficiency virus and *Mycobacterium tuberculosis*), or suspect Monkey Pox it must be mentioned in the clinical details sent with the specimen.

5) If you suspect, or are aware of, an infection with a Hazard Group 4 pathogen (Viral haemorrhagic fevers, e.g., Ebola and Lassa) do not attempt to collect any specimen. Inform the Infection Control Doctor for the Trust through switchboard.

When you have finished all waste generated from obtaining a specimen should be disposed of according to Local Waste Disposal Protocols.

#### 7.1 Procedure for venepuncture to obtain a specimen of blood / blood cultures.

Please refer to the Trust's intranet site for guidance on this procedure.

#### 7.2 Procedure for the collection of pus or exudates

Where there are clinical signs of infection i.e., inflammation, oedema, pyrexia, pain or purulent. exudate, it is preferable to obtain a specimen of pus rather than to take a swab.

Pus or exudate can be drawn up in a syringe and transferred to a universal container.

Taking a Transwab (blue top) or Charcoal swab (black top), remove the swab and gently but firmly rotate it on the surface directly where infection is suspected. Do not take swabs from slough or necrotic tissue. Place the swab into the transport medium.

Ensure that the specimen containers are labelled accurately and place, with the completed request form, in the appropriate pockets of the clear mini-grip transport bag for transportation to the Department of Medical Microbiology (via Pathology).

Specimens should be transported and processed as soon as possible.

The volume of specimen influences the transport time that is acceptable. Large volumes of purulent material maintain the viability of anaerobes for longer.

The recovery of anaerobes in particular is compromised if the transport time is delayed.

If processing is delayed, refrigeration is preferable to storage at ambient temperature.

#### 7.3 Procedure for the collection of screening swabs (MRSA, CPE, VRE)

These swabs should only be taken on the advice of the Community Infection Control Team or to comply with individual hospital protocols. They are taken to ascertain whether a patient is colonised with potentially pathogenic bacteria e.g., MRSA, VRE, CPE. If clinical infection is suspected, please send another swab from ulcers, wounds etc. separately for MC&S.

#### **MRSA** culture

For routine MRSA screens nose and groin swabs are required. Axillae swabs are only tested from pre-pacemaker insertion patients on CCU and CCS.



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#### Collection:

**Nasal** – rotate the swab gently but firmly around the anterior nares of each nostril. One swab can be used for both nostrils.

**Groin –** rotate the swab gently but firmly over each area. One swab can be used for both groins.

#### MRSA PCR (CoCH only)

Only nose and groin swabs from patient on ITU at CoCH are tested for MRSA by PCR. Swabs from contact screens or any other patient are only tested by PCR if requested by the Infection Control Nurses at CoCH. **Pink topped liquid swabs are required for MRSA PCR** – contact Infection Control if guidance is required.

#### **CPE / VRE culture**

Using a Transwabs (blue or black top), take a rectal swab – refer to Trust guidelines for guidance on collection.

#### **CPE PCR (WUTH only)**

Refer to Infection Control policies for guidance on which patients require molecular testing for CPE. Using a **dual** swab (red top), take a rectal swab – refer to Trust guidelines for guidance on collection.

#### **VRE PCR (CoCH only)**

Refer to Infection Control policies for guidance on which patients require molecular testing for VRE. Using a **dual** swab (red top), take a rectal swab – refer to Trust guidelines for guidance on collection.

Ensure that swabs are labelled accurately. Place, with the completed request form, in the appropriate pockets of the clear minigrip transport bag for transportation to the Department of Medical Microbiology (via Pathology).

Specimens should be transported and processed as soon as possible.

#### 7.4 Procedures for the collection of Urogenital Samples

**N.B.** If an expanded screen for sexually transmitted diseases is required, the patient should be referred to the local Sexual Health Service.

## 7.4.1 Collection of urogenital samples for Microscopy, Culture & Sensitivity (MC&S)

#### High vaginal swabs and Cervical/Endocervical swabs

Place the patient in dorsal position, supported by a pillow and ask her to bring her heels together, bend her legs and then draw her heels towards her bottom.

Moisten the speculum with warm water and insert into the vagina to separate the vaginal walls. Wipe away any excess cervical mucus with a tissue.

**HVS:** Using a blue or black topped swab, sample as high as possible into the vault and swab the vaginal wall.



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**Cervical/endocervical swab**: Using a blue or black topped swab, gently insert a swab into the endocervical canal and rotate to obtain any exudate. Try to avoid contact with the vaginal mucosa when removing the swab.

Remove speculum and wipe vaginal / vulval area with a tissue.

Ensure that the swab is labelled accurately and place with the completed request form, in the appropriate pockets of the clear minigrip transport bag for transportation to the Department of Medical Microbiology (via Pathology).

NB. Charcoal based transport swabs prolong the survival of *gonococci* compared to non-charcoal-based swabs.

#### Low vaginal swab

Place the patient in dorsal position, supported by a pillow and ask her to bring her heels together, bend her legs and then draw her heels towards her bottom. Insert the swab into the lower part of the vagina and rotate gently but firmly.

Ensure that the swab is labelled accurately and place, with the completed request form, in the appropriate pockets of the clear minigrip transport bag for transportation to the Department of Medical Microbiology (via Pathology).

#### **Urethral swabs**

Avoid contamination with micro-organisms from the vulva or the foreskin. Small swabs are available for the purpose. The patient should not have passed urine for at least 1 hour. For males, if discharge is not apparent attempt to "milk" it out of the penis. Pass the swab gently through the urethral meatus and roll around. Place the swab in the plastic transport sheath containing the black charcoal containing Amies medium. NB specimens for Chlamydia investigations should be collected after the swab for MC&S.

All specimens should be transported and processed as soon as possible. If processing is delayed, refrigeration is preferable to storage at ambient temperature.

#### 7.4.2 Collection of urogenital samples for molecular investigations

Urogenital samples for molecular investigations should be collected as per collection for samples for MC&S, but the samples should be collected using the following specimen containers:

Chlamydia trichomonas / Neisseria gonorrhoea (CT/NG) and Trichomonas vaginalis (TV) PCR

#### For all requestors

If Chlamydia/gonorrhoea infection is suspected, swabs or urine can be submitted for analysis. The sample must be collected/placed into the appropriate Roche Cobas **Un**i Swab/urine container. (available from NHS Supplies or under contract from Liverpool Clinical Laboratories).

- Roche Cobas Uni Swab (clinical and self-taken samples)
- Roche Cobas **Un**i Swab (urethral, oropharyngeal & rectal samples)
- Roche Cobas DUAL swabs (for endocervical samples)
- Roche Cobas Urine Collection tube (for first catch urine from males or females)



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NB Investigation for *Trichomonas vaginalis* (TV) can be performed on self-taken vaginal swabs placed in a Roche Cobas **Un**i Swab **BUT** TV processing will only be performed if specifically requested.

Following specimen collection, store the Cobas PCR Media tube containing the specimen swab at 2-30°C. The specimen is viable for up to 3 months.

#### 7.5 Procedure for the collection of sputum

The material required is fresh sputum from the lower respiratory tract, expectorated by deep coughing. When the cough is dry, physiotherapy, postural drainage or inhalation of an aerosol may be helpful. Saliva and postnasal secretions are not suitable. Early morning specimens for examination of *Mycobacterium species* should be collected on at least 3 consecutive days.

Routine sputum microscopy is not worthwhile, but will be done urgently where Staphylococcal pneumonia is suspected or where specifically requested.

Ensure that the specimen container is labelled accurately and place, with the completed request form, in the appropriate specimen transport bag for transportation to the Department of Medical Microbiology (via Pathology).

Collect specimens before starting antimicrobial therapy where possible.

BAL and sputum should be processed promptly to give the best opportunity to culture pathogenic organisms and reduce the risk of overgrowth with contaminants.

If processing has to be delayed up to 24 hours, refrigeration is preferable to storage at ambient temperature.

#### **Bronchial Lavage**

Please inform the laboratory for urgent processing.

NB. Legionella/PCP investigations – please contact the Laboratory if required.

## 7.6 Collection of a mid-stream specimen of urine (MSSU) for culture and sensitivity

#### Ensure that the patient is physically clean.

If the patient has had the perineum washed in the last 12 hours (i.e., has had a shower or bath), further cleansing of the perineal area before urine collection is not necessary.

#### If the patient:

- Is incontinent and / or:
- Has had their bowels opened since washing the area:

The collection of urine must be postponed until the perineal area has been washed.



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Catch the middle portion of the urine in a clean wide-mouth receptacle. Such a receptacle need not be sterile: any container, previously washed thoroughly with detergent and hot water and stored dry, is suitable.

A sample of the middle portion of the urine must be poured into a 20ml **red** capped universal container (boric acid) with all sections on the label completed. Very small samples from paediatric patients only may be collected into a 20ml white capped sterile universal (white capped samples MUST be received in the lab **within 4 hours** of collection).

If processing is delayed for up to 48hr, refrigeration is essential. Alternatively, the specimen may be collected in a CE marked leak proof container with boric acid preservative. This increases the maximum permissible time for transport to the laboratory to up to 96hr.

#### 7.7 Collection of a specimen of urine from a catheter (CSU)

When small volumes of fresh urine are required for laboratory investigations, the distal end of the catheter, or preferably the sampling port if present, must be disinfected with 70% isopropyl alcohol and urine aspirated with a sterile syringe.

The urine must be transferred to a 20ml red capped universal container (boric acid) with all sections on the label completed.

If large volumes of urine for laboratory tests are required, these should be obtained aseptically from the drainage bag.

#### 7.8 Procedure for the collection of a specimen of faeces

When collecting a specimen of **Faeces** it should be obtained in a convenient container and transferred into a sterile container with a wooden disposable spatula.

#### Minimum volume of sample:

- A liquid specimen of 1-2ml is sufficient.
- 1 gram (large pea-size) of solid specimen

Rectal swabs are not a reasonable substitute for faeces: except for CPE/VRE screening.

Faeces for parasites – the recommendation is 3 specimens taken on different days for optimum recovery.

Ensure that the specimen container is labelled accurately and place, with the completed request form, in the appropriate specimen transport bag for transportation to the Department of Medical Microbiology (via Pathology).

For the detection of ova of Enterobius vermicularis (threadworm): use with a plain swab, moisten with sterile saline, wipe firmly around the anal margin and place the swab into a sterile universal container.

Important pathogens such as Shigella species may not survive the pH changes that occur in faecal specimens if not promptly delivered to the laboratory, even if refrigerated. If processing is delayed, refrigeration is preferable to storage at ambient temperature.



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#### 7.9 Procedure for the collection of a pernasal swab

Gently insert the fine, flexible pernasal swabs (sky blue top) swab horizontally to the back of the nose. If obstruction is encountered, withdraw and re-insert through the other nostril.

Ensure that the swab is labelled accurately and place, with the completed request form, in the appropriate specimen transport bag for transport to the Department of Medical Microbiology (via Pathology).

Collect specimens before antimicrobial therapy where possible.

Specimens should be transported and processed as soon as possible. If processing is delayed, refrigeration is preferable to storage at ambient temperature.

#### 7.10 Aspirates and fluids from normally sterile sites

Collect the specimen with a sterile syringe. Transfer a maximum 20ml into a sterile universal container. Ensure the cap is tightly screwed on.

Specimens should be transported and processed as soon as possible. If acute infection is suspected and the result may affect medical management, receive and process the sample within 4 hours. The result for microscopy should be made available within 2hr of the Gram stain. If processing is delayed, refrigeration is preferable to storage at ambient temperature.

#### 7.11 Cerebrospinal fluid

? Meningitis - An adequate amount is essential – send at least 2-3ml. Label the samples as you collect them as the lab need to know which sample is the most valuable for cell count and culture. This is particularly important if *Mycobacterium tuberculosis* infection is suspected where small numbers of organisms may be present. For exclusion of mycobacterial CNS infection at least 6mls CSF is required: this will be processed by Microbiology at Manchester Royal Infirmary. If there are smaller volumes then an automated comment will be produced indicating low volume. The results of microscopy and any positive cultures are always telephoned.

? Subarachnoid haemorrhage (SAH) if there is a clinical suspicion of SAH and the specimen is bloodstained send the 1<sup>st</sup> and 3<sup>rd</sup> samples so that differential red blood cell counts may be performed. The results of microscopy and any positive culture are always telephoned. Always inform the laboratory if SAH is a possibility.

Time between collection to microscopy and culture should occur within a maximum of 2 hours. Cells disintegrate and a delay may produce a cell count that does not reflect the clinical situation of the patient. Specimens should be transported and processed as soon as possible. Do not refrigerate specimen until after microscopy and bacterial culture have been performed. The specimen should then be refrigerated pending further investigation.

#### 7.12 Wound Swabs

Decontaminate the skin to remove as much of the superficial flora. Using a blue or black topped transwab, remove the swab and gently but firmly rotate it on the surface directly where infection is suspected. Do not take swabs from slough or necrotic tissue. Place the swab into the transport medium. If pus is present send as much as possible in a sterile universal container.



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Specimens should be transported and processed as soon as possible. If processing is delayed, refrigeration is preferable to storage at ambient temperature.

#### 7.13 Collection of specimens for mycology investigations

#### Skin

Patient's skin and nails can be swabbed with 70% alcohol prior to collection of the specimen, this is especially important if creams, lotions or powders have been applied. The edges of skin lesions yield the greatest quantities of viable fungus. Lesions should be scraped with a blunt scalpel blade.

#### **Nails**

Good nail samples are difficult to obtain. It should be specified whether the sample is from the fingernails or toenails. Material should be taken from any discoursed, dystrophic or brittle parts of the nail. The affected nail should be cut as far back as possible through the entire thickness and should include any crumbly material. Nail drills, scalpels and nail elevators may be helpful but must be sterilized between patients. When there is superficial involvement (as in white superficial onychomycosis) nail scrapings may be taken with a curette. If associated skin lesions are present, samples from these are likely to be infected with the same organism and are more likely to give a positive culture.

#### Hair

Samples from the scalp should include skin scales and plucked hairs or hair stumps. Cut hairs are not suitable for direct examination as the infected area is usually close to the scalp surface. Plastic hairbrushes, scalp massage pads or plastic toothbrushes may be used to sample scalps for culture where there is little obvious scaling but such samples do not replace a scraping for direct examination.

Collect specimens before antifungal therapy where possible. Specimens should be transported and processed as soon as possible.

Specimens should be kept at room temperature and transported and processed as soon as possible although, provided the samples are kept dry, the fungus will remain viable for several months. Samples should be allowed to dry out and kept at room temperature.

#### 7.14 Blood for Virology/Serology investigations

For antibody and antigen assays collect blood in a blood collection tube (red or ochre cap) – 4mls (Wirral), - 8mls (Chester).

For viral DNA/RNA Polymerase Chain Reaction (PCR) tests please send two 4ml EDTA tubes (purple cap) – (Wirral and Chester).

 $\beta$ -D-Glucan any tube with clotting accelerator(red or ochre cap). The test is not validated for sputum specimens.

#### Paediatric blood tubes

 Chester EDTA = Red Clotted blood = Brown MMSOP30 Page 22 of 51

 Wirral EDTA = Purple Clotted blood = Red

For the various virology/serology investigations available refer to **Section 10 Investigations** and **Turnaround Times** 

Specimens should be transported and processed as soon as possible.

If processing is delayed, refrigeration is preferable to storage at ambient temperature.

#### 7.15 Swabs for viral investigations

Moisten the plastic shafted swab with sterile saline never with Viral Transport Media (VTM) before swabbing. Using a sterile saline moistened plastic shafted swab, swab the area concerned or vesicles, if vesicles present burst vesicle with sterile needle and swab fluid released. Snap off the swab tips into VTM.

Transport as soon as possible at ambient temperature.

If transport is delayed, samples may be stored at room temperature for up to 24 hours.

### 7.16 Fluids and Pus for viral investigations

Collect as much fluid/pus as possible in a universal container.

#### 7.17 Corneal Scrapes

#### Collection

A standard operating procedure is available in the Eye Clinic; the following is a summary of this document.

## During Core Laboratory Hours - Mon - Sun 08-45 - 19-00.

1. Please contact the Consultant Microbiologist, to discuss the case.

Two corneal scrape kits (containing a bijoux of broth and a glass slide) are kept in the Ophthalmology Clinic and a further kit is kept in the A+E department. The lab sends these kits to Ophthalmology upon request. To request further kits please telephone the Microbiology Department between 9am-4pm Monday to Friday (01244 362500)

Specimens should be transported and processed as soon as possible. If processing is delayed, refrigeration is preferable to storage at ambient temperature.

If specimens for investigation for amoebae cannot be processed within 8hr, it is preferable to store them at ambient temperature.

Do not freeze specimens.



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#### 7.18 Nose and throat swabs/Nasal Aspirations

A single swab can be used. Swab the throat first then nose and place into one pot of viral transport medium; OR

If 2 swabs in the pack, place BOTH the throat & nose swab into the same VTM.

Taking throat swabs: Ask patient to open mouth wide. Using swab, vigorously swab only the posterior pharyngeal wall.

Taking nose swabs: Tilt head back slightly and gently insert swab along the medial part of the septum. Rotate swab several times and remove.

The shafts of the swabs should be broken off at the break point so that they fit into the VTM container. Firmly secure cap.

Aspirates should be placed in dry sterile specimen container. Ensure the cap is tightly screwed on

Order the correct PCR tests and label the specimen accordingly.

Specimens should be transported and processed as soon as possible.



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#### 8.0 TRANSPORT OF CLINICAL SPECIMENS FROM WIRRAL

#### 8.1 Specimens collected and sent from Arrowe Park Hospital

#### **Monday to Friday**

**From 09-00hrs. until 14-00hrs daily** there is an hourly collection of Pathology specimens from wards by the portering staff.

After 14-00hrs bleep porters on 2145 to pick up specimens (except Blood cultures which should be sent by pneumatic tube or taken to Specimen Reception at Laboratory Medicine, Arrowe Park). Blood cultures must be sent to pathology immediately after collection to ensure they are stored in the correct conditions.

The last routine transport from Arrowe Park Hospital to the diagnostic Laboratory at Bromborough is at **16-45hrs**.

#### Weekend and Bank Holidays

**At approximately 09-00hrs** a single collection from the ward is made by the portering staff.

If specimens miss the collection, then they should be sent to the Arrowe Park Specimen Reception.

There is a scheduled pick-up of specimens, by van, from Arrowe Park Pathology Laboratory until 15-00hrs.

#### **Urgent Specimens – Normal Hours (Mon-Sun)**

If specimens require urgent processing during normal working hours, then please contact the Microbiology Department and inform us of the patient, the ward and any tests required on Extension **4511**. Arrange delivery by telephoning the Porters to request urgent collection of samples to be taken directly to the Pathology Laboratory Specimen Reception. Refer to **Section 8.4 Packaging and Transport** for guidance on packaging samples for transport by taxi.

#### **Urgent Specimens – Out of Hours (Mon-Sun)**

Weekdays 18-30 – 09-00hrs, Saturday, Sunday and Bank Holidays an out of hours service is available. The Biomedical Scientist can be reached by the Hospital switchboard. Clinical advice is always available from the Consultant Microbiologist (available through the Hospital switchboard).

Do not send specimens to Microbiology Department during 'Out of Hours' unless instructed to do so by the Biomedical Scientist.



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#### 8.2 Specimens collected and sent from Clatterbridge General Hospital

#### **Monday to Sunday**

Specimens need to be taken to the first floor Blood Science Lab at CCC Drivers will collect CGH samples every hour from 09-00hrs. This Service will run between CGH, APH and the Microbiology lab at Bromborough on a continuous loop. The last collection from CCC is at 16-30. Any non-urgent samples that will not be ready for transport by 16-30 should be refrigerated and made ready for transport the next day.

For URGENT specimens only after 18-30hrs please contact the Out of Hours BMS, via Arrowe Park Switchboard.

#### 8.3 Specimens collected and sent from GP Practices

Samples from General Practice for Laboratory Medicine will be collected by a hospital courier or SRCL/ERS Courier Service Monday to Friday only.

#### 8.4 Packaging and transport

Before the specimens are collected by porters, couriers, volunteers, nursing and support staff ensure that specimens and request forms are placed correctly into the min-grip plastic bags. Specimens should be placed in the pocket of the plastic bag and grip seal sealed. The request form should be slid into the sleeve of the plastic bag. The specimen should then be placed in the large Blue Microbiology specimen bags (with an absorbent material to comply with United Nations standard Packing Instruction P620) for collection. All microbiology specimens that are not collected promptly should be refrigerated, unless otherwise stated in this guide.

Specimens that are to be transported by taxi from the hospital to the main Microbiology Laboratory must be packaged in a robust container and **no** patient details should be visible on the outer packaging – refer to the European Agreement Concerning the International Carriage of Dangerous Good by road (ADR2021).

**N.B** The plastic transport bags, if properly sealed, are designed to contain accidental specimen leakage from the container. Spontaneous specimen discharge, due to defective materials, is rare. Most incidents of specimen leakage are due to the fact that neither the container nor the integral bag strips have been closed properly. If both container and transport bag are closed correctly, the practice of 'double-bagging', even when an infection with a Hazard Group 3 pathogen is suspected, does not confer any additional safety advantage and is, therefore, unnecessary

The containers supplied, comply with standards BS4851 and BS5213 for leakage and spontaneous discharge. Leaked containers frequently result in irreplaceable loss of specimens and, equally as important, staff to unwarranted hazards of infection.

Members of the public who come across large blue specimen bags containing specimens should telephone the lab.



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#### 9.0 TRANSPORT OF CLINICAL SPECIMENS FROM CHESTER

#### **Routine Specimens**

Specimens are delivered to the Microbiology Dept (via Pathology) throughout the working day, Monday – Friday, from the Pathology Laboratory reception via hospital transport vans. However, the last collection of the day leaves there at 17-00hrs. Therefore, specimens must have reached the pathology laboratory reception by the porters, well in advance of this time. Samples will be collected from Pathology throughout the day on Saturday and Sunday up until 15-00hrs. Routine samples may be transported to Pathology via the pneumatic air tube system providing the samples are correctly packaged with secure lids, except for CSF samples.

#### **Urgent Specimens – Normal Hours**

If specimens require urgent processing during normal working hours, then please contact the Microbiology Department and inform us of the patient, the ward and any tests required on Extension 2500. Arrange delivery by telephoning the Porters to request urgent collection of samples to be taken directly to the Pathology Laboratory Specimen Reception. Refer to **Section 9.1 Packaging and Transport** for guidance on packaging samples for transport by taxi.

#### **Urgent Specimens – Out of Hours**

Weekdays 18-30 – 09-00hrs, Saturday, Sunday and Bank Holidays an out of hours service is available. The out of hours Biomedical Scientist can be reached by the Hospital switchboard. Clinical advice is always available from the Consultant Microbiologist (available through the Hospital switchboard).

Do not send specimens to Microbiology Department during 'Out of Hours' unless instructed to do so by the Biomedical Scientist.

9.1 Packaging and transport

See Section 8.4

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## 10.0 INVESTIGATIONS AND TURNAROUND TIMES

For specimen collection see Section 7

Specimen Investigation	Specimens and Comments	Referred to	Turnaround times
Adenovirus PCR	Broncho-alveolar lavage	Ref Lab*	2-5 days
/ donovirdo i orc	CSF	_	2 o dayo
	Eye swab		
	Urine Urethral swab		
	EDTA blood preferred.		
Amoebic Antibodies	Clotted blood	6	5-7 days
Antenatal Screen: Hepatitis B surface	Clotted blood		1-5 days
antigen/HIV/Syphilis/	Antenatal rubella no longer advised		
(Rubella)	A serior and the series of the		
Staphylococcal	Clotted blood	1	5-7 days
Antibody			
(reference lab test-			
availability limited so			
needs discussion with			
Consultant Microbiologist)			
Wild obloid gist)			
Anti Streptolysin-O	Clotted blood	4	5-7 days
antibody and			
anti streptodornase			
Arbovirus	Clotted blood	3	5-7 days
Carlodes Flavidoses	EDTA Blood		
(includes Flaviviruses such as West Nile,	Urine		
yellow fever, dengue	REQUEST CAN ONLY BE MADE IN		
and Alphavirus such	CONSULTATION WITH A		
as chikungunya,	MICROBIOLOGY CONSULTANT		
Ross River, EEE, WEE			
			_
Aspergillus Antibodies	Clotted blood		5-7 days
	(Immunology Request at Chester)		
Aspergillus antigen	Clotted blood	10	2-5 days
(Galactomannan)			



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Aspergillus PCR	Bronchoalveolar Lavage Sputum	2	2-5 days
	EDTA Blood	4	5-7 days
Aspirates and fluids from normally sterile			2-5 days
sites (joint, ascites, peritoneal and pleural fluids)			Urgent Cell Count/Gram Stain 1 Hour from receipt
Avian Precipitins	Clotted blood (Immunology requests at Chester)		10 days
Atypical Pneumonia	For Legionella please send urine sample for Urinary Legionella Antigen	M.	
	Mycoplasma pneumoniae serology available: clotted blood	2	2-4 days
	Molecular techniques i.e., PCR looking for Viruses, mycoplasma, pertussis etc. require. respiratory tract samples e.g., Sputum,		
	BAL. NPA: In clear universal container, or trap.  Nose and throat swab / NP swab in VTM		
Bartonella (cat scratch)	Specific test for Bartonella no longer available – please contact Consultant Microbiologist for further advice.		
BK/JC PCR	EDTA Blood CSF	2	2-5 days
Haemorrhagic cystitis	001		
Progressive multifocal leukoencephalopathy			
Renal transplant			
Blood Cultures for	Blood culture set = Aerobic (blue or green		Up to 5 days
diagnosis of sepsis, bacteraemia and	top) AND anaerobic (purple top) blood culture bottles (adults / adolescent) 4-10ml		(incubated for 5 days
infective endocarditis	blood per bottle Inoculate O <sub>2</sub> bottle first		before being
Blood cultures must be sent to pathology	Paediatric bottle (yellow top) 1-4ml blood		discarded as negative)
immediately after collection to ensure	Culture is no longer extended beyond 5 days, if endocarditis is suspected contact		



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they are stored in the correct conditions.	the Consultant Microbiologist as it may be appropriate to refer an aliquot of the blood culture samples for 16s (pan-bacterial PCR)		
	Normally sterile body fluids may also be inoculated into blood culture bottles.		
Bordetella pertussis Serology	Clotted blood	1	5-7 days
Pertussis (whooping cough)			
Bordetella PCR	Throat swab in viral transport media	2	5-7 days
Pertussis (whooping cough)	or pernasal swab		
Brucella serology	Clotted blood	8	5-7 days
Bronchoalveolar Lavage (Washings)	Send washings in a sterile universal. container		2-5 days
Campylobacter Serology	Clotted blood	1	5-7 days
Candida PCR	EDTA Blood BAL	2	5-7 days
Candida Precipitins	Clotted blood	4	5-7 days
Catheter specimen of urine (CSU)	Transfer urine to a sterile universal container (>3ml)		48 hours
Cervical swab	For the culture of gonorrhoea use a Black topped Microbiology (Charcoal) swab and transport to the laboratory Immediately. (Urethral, rectal and throat swabs may also be collected and sent for gonorrhoea culture).		2-4 days
	For virology investigation send a swab in virus transport medium		
Chlamydia (MIF) Serology	Clotted blood		3-5 days



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Chlamydia eye swabs	For investigation of <i>C.trachomatis</i> Infection in the eye, send a swab from the conjunctiva in a VTM/ Roche Cobas UNI swabs collection tube.		3-5 days
Clostridium difficile toxin*  C.difficile PCR*	Detection of Clostridium difficile cytotoxin in faeces of patients with antibiotic associated diarrhoea, antibiotic-associated colitis, or Pseudomembranous colitis.		24 hours
*See Appendix 1 for interpretation of results	Transfer 1 gram (large pea-size) portion of faeces, or 1-2 ml volume of liquid specimen, into a sterile universal container.  Only diarrhoeal stools will be tested.		
CMV IgM	Clotted blood		1-4 days
CMV IgG CMV IgG avidity	Clotted blood	9	1-4 days
CMV PCR	EDTA Blood preferred. Sputum, Placenta Urine Amniotic fluid Tissue	2	2-5 days
Corneal scrapes	Corneal scrape kits (containing a bijoux of broth and a glass slide). Please indicate on the slide which side has been inoculated using a pencil to write on the frosted area. Kits can be obtained from Microbiology during 9am – 4pm Monday to Friday.		2-7 days Urgent Gram stain 1 hour from receipt
Covid PCR	Nose/Throat swabs in viral transport media (both swabs in same tube)  Nasopharyngeal aspirate  NB testing performed 24/7 at CoCH.	9	Cepheid 1-3 hours
Covid antibodies IgM and IgG combined	Clotted blood		5 days
Coxsackie B virus serology – no longer available, but serum may be tested for enteroviruses by PCR	Clotted blood EDTA Blood	2	3-5 days



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Culture for bacterial infections	Pus is the ideal specimen or a biopsy of the infected tissue. Send in a sterile universal container. If only a small sample of tissue is available, add a few drops of sterile normal saline to prevent drying. If swabs are taken, use black topped Microbiology (Charcoal) swab or blue topped Microbiology swab (Transtube) – refer to Wound and Ulcer Swabs		2-5 days
Creutzfeldt-Jakob Disease (CJD)  ONLY IN CONSULTATION WITH FIRSTLY THE NATION CJD REFERENCE UNIT (0131 537 2128) and SECONDLY MEDICAL MICROBIOLOGY CONSULTANT	>1ml CSF, only accepted if <150 RBC on microscopy. CSF sent to lab for cell count. Lab will freeze at -80°C and send via courier to:  The National Creutzfeldt-Jakob Disease Research & Surveillance Unit Western General Hospital Crewe Road Edinburgh EH4 2XU  See http://www.cjd.ed.ac.uk for Contacts		1-2 weeks
Cryptococcus antigen testing	Clotted blood >1ml CSF in a sterile universal container	2	2-3 days
Cerebro Spinal Fluid (CSF)	Bacterial Meningitis >1ml CSF in a sterile universal container		48 hours Urgent Microscopy 1 hour from receipt
CONTIN	<ul> <li>Viral Meningitis/Encephalitis &gt;1ml CSF in a sterile universal container</li> <li>Sub Arachnoid Haemorrhage please send the first and third specimen &gt;1ml CSF in a sterile universal container</li> <li>Mycobacterial Meningitis 6ml CSF in a sterile universal container</li> <li>PCR Screen: &gt;1ml CSF in a sterile universal container</li> </ul>	2	3 days  48 hours Urgent Microscopy 1 hour from receipt  7-14 days  3 days
	Preliminary cell counts and Gram Stain		



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	Clotted blood results will be telephoned to the sending location as soon as possible after receipt of the specimen and released as preliminary results for viewing on CERNER		
Delta Antibody (Hepatitis D)	Clotted blood	2	5-7 days
Delta PCR (Hepatitis D RNA)	EDTA Blood	1	7-10 days
Dengue Virus	Clotted blood (Antibody) EDTA Blood (PCR) Urine (PCR)	3	5-7 days
Diphtheria Antibodies	Clotted blood	2	1-2 weeks
Ear swab	Send a swab in black topped Microbiology (Charcoal) swab or in blue topped Microbiology swab (Transtube)	),	2-4 days
Early morning urine for tuberculosis	First catch urine in the morning collect in a sterile universal container, must send 3 consecutive samples		6-8 weeks
Enterobius vermicularis (Threadworm)	With a plain swab, moistened with sterile saline, wipe firmly around the anal margin and place the swab into a universal container		24 hours
Epstein-Barr virus serology – detection of EBV VCA IgG, VCA IgM, EBNA antibodies	Clotted blood		1-4 days
Epstein Barr Virus PCR	EDTA Blood CSF Tissue Throat swab in VTM	2	2-5 days
Eye swab	Send a swab in black topped Microbiology (Charcoal) swab or blue topped Microbiology swab (Transtube)  For detection of Chlamydia trachomatis and/or Neisseria gonorrhoea by PCR refer to Sexual Health Screening		2-4 days
	Send a swab in virus transport medium for virology if required.		



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Enterovirus PCR	Clotted blood EDTA Blood CSF Vesicle swab in VTM Throat swab in VTM Faeces	2	2-5 days
Farmers Lung	Clotted blood (Immunology in Chester)		5-7 days
Faeces PCR (VTEC E.coli, Shigella, Salmonella, Campylobacter, Cryptosporidia, Giardia)	Transfer 1 gram (large pea-size) portion of faeces, or 1-2 ml volume of liquid specimen, into a sterile universal container		2-3 days
Faeces culture	E.g. to confirm positive PCR results or clearance of food handlers	),	
Ova, cysts and parasites.	Please indicate any foreign travel / country of travel		
Filariasis Antibodies	Clotted blood	6	5-7 days
Galactomannan (See Aspergillus antigen above)		10	
Glucan (β-Dglucan)	Invasive fungal infection		
	Clotted blood	10	2-5 days
Haemophilus Influenzae B (HIB) Antibodies	Clotted blood	2	2-3 weeks
HIB PCR	EDTA Blood CSF	2	5-7 days
Helicobacter Pylori Stool Antigen	Transfer 1 gram (large pea-size) portion of faeces, or 1-2 ml volume of liquid specimen, into a sterile universal container  The test must be carried out within 72 hours of taking the specimen.  PLEASE ENSURE THE PATIENT RECORDS THE DATE AND TIME OF COLLECTION ON THE FORM/ SAMPLE		1-3 days



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Hepatitis A IgM	Serology: detection of IgM antibody in jaundiced patients		1-4 days
	Clotted blood		
	Positive serology may indicate recent infection. Confirmation will follow – HAV PCR on serum		
Hepatitis A IgG	Immune status assessment:		1-4 days
	IgG serum antibody, when considering active or passive immunisation		
Hepatitis B infection	Clotted blood Serology: detection of surface antigen and		1-4 days
Hepatitis B illiection	core IgM antibody in jaundiced patient		•
	Clotted blood	210	Urgent 1-3 hours from receipt (if received
			between 9:00 – 17:30)
Hepatitis B PCR	Quantitative PCR: To indicate viral load	2	1-4 days
	Sequencing for genotype and antiviral Resistance		
	EDTA Blood		
	If EDTA not available use serum		
Hepatitis B e Antibody/Antigen	Clotted blood		1-4 days
Hepatitis B immunity	Immune status: Assessment of surface antibody, or to verify sero-conversion, following vaccination		1-4 days
Hepatitis B	Clotted blood Clotted blood		1-4 days
Surface Antigen	Ciolica bioda		Urgent 1-3 hours (if received between 9:00 – 17:30)
Hepatitis C	Serology, detection of viral antibody		1-4 days
screen	Clotted blood		Urgent 1-3 hours



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			(if received between 9:00 – 17:30)
Hepatitis C PCR/ Genotype	Quantitative PCR: To indicate viral load  Qualitative PCR for genotype	2	1-4 days
	EDTA Blood If EDTA not available use serum		
Hepatitis E IgM Antibody	Clotted blood	2	3-5 days
High Vaginal swab (HVS)	Send a swab in black topped Microbiology (Charcoal) swab or blue topped Microbiology swab (Transtube)	Olk	2-4 days
	For suspected PID or detection of Chlamydia trachomatis, Neisseria gonorrhoea or Trichomonas vaginalis by PCR refer to Sexual Health Screening	),	
HIV 1 & 2 Antibody and P24 Antigen	Clotted blood		1-4 days  Urgent 1-3 hours (if received between 9:00 – 17:30)
HIV Viral Load	EDTA blood  (For neonates pro-viral DNA may be requested-whole blood on EDTA, must not be separated)	2	2-5 days
HIV Resistance Testing	Characterising the genotype of the HIV virus and enhancing this by matching to the database of phenotypes for the HIV gives a virtual phenotype of the HIV virus. This leads to an understanding of the resistance mechanisms that might be present.  EDTA blood	2	7-10 days
HSV 1 & 2 Antibody	Clotted blood  Both HSV total antibody and type specific	2	2-5 days



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	antibody available.		
HSV 1 & 2 PCR	>1ml CSF Neonatal blood Vesicles Respiratory samples EDTA blood tube	2	1-4 days
HTLV I/II Antibody	Clotted blood		2-5 days
HTLV-1 PCR	EDTA Blood	1	5-7 days
Human Herpes Virus 6 PCR	EDTA Blood CSF	2	5-7 days
Human Herpes Virus 7 PCR	EDTA Blood CSF	2	5-7 days
Human Herpes Virus 8 PCR	EDTA Blood Tissue Fluid (effusion)	1	5-7 days
Hydatid, Malaria, Schistosoma and Amoeba antibody tests	Clotted blood	6	5-7 days
Infection Control screen (MRSA screen)	Nose and groin swabs  Send a swab in black topped Microbiology (Charcoal) swab or blue topped Microbiology swab (Transtube)		1-4 days
Infection Control screen (Resistant Gram Negative Organisms (CPE) screen)	Rectal swab  Send a swab in black topped Microbiology (Charcoal) swab or blue topped Microbiology swab (Transtube)		1-4 days
Infection Control screen (VRE screen)	Rectal swab  Send a swab in black topped Microbiology (Charcoal) swab or blue topped Microbiology swab (Transtube)		2-4 days
Infection Control Screen rapid molecular testing (Cepheid)	CPE PCR: Red top dual swab (rectal swab) (APH only)		24 hours 2-3 hours
(Sopriola)	MRSA PCR:		



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	Pink top liquid swab (nose & groin swabs) (Chester-ITU only)  VRE PCR: Red top dual swab (rectal swab) (Chester-ITU only)		(if received between 9:00 – 17:30)
Influenza Virus A/B PCR	Nose/Throat swabs in viral transport media (both swabs in same tube)		24 hours
+	Nasopharyngeal aspirate		1-3 hours (if received between
Respiratory Syncytial Virus (RSV) PCR	NB testing performed 24/7 at CoCH		9:00 – 17:30)
Intrauterine contraceptive device (IUCD)	Send the device in a sterile universal Container.  NB. IUCDs are not routinely processed and will only be processed if clinical details state there is a suspicion of infection.		2-4 days
=	Culture for Actinomyces sp		10-12 days
Joint Fluids	>1ml in a sterile universal container + lithium heparin tube for 'hot' joints ('hot joint' packs available from specimen reception at WUTH only)  If the specimen is urgent preliminary cell count and gram stain will be telephoned to the sending location as soon as possible after receipt of the specimen and		2-5 days  Urgent Microscopy 1-2 hours from receipt
Legionella Antigen (detects Legionella pneumophila Serogroup 1 only)	preliminary report released electronically.  >3ml Urine in a sterile universal		Same day as receipt
Leptospira Antibody	Clotted blood	3	5-7 days
Leptospira PCR	EDTA Blood Urine		5-7 days
Lyme Disease (Borrelia burgdorferi) Antibody	Clotted blood		1-4 days
Malaria Antibody	Clotted blood	6	5-7 days
Measles IgM Antibody	Clotted blood	2	2-4 days



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Measles IgG Antibody	Clotted blood		5-7 days
			Urgent
			1-3 hours
			from receipt
Measles PCR	>1ml CSF	2	1-4 days
Please inform lab	EDTA blood		
about sample			
dispatch			
Meningococcal	Clotted blood	2	2-3 weeks
Antibodies (vaccine			
Functional antibodies:			
Serological tests			
for specific antibodies after vaccination)			
aitei vacciiiatiori)			
Meningococcal &	CSF	2	1-4 days
Pneumococcal PCR			
	EDTA Blood		Urgent 1 day
If urgent, please			
inform lab about sample dispatch			
Sample dispatch			
Mouth swab	Send a swab in Blue topped Microbiology		2-4 days
	swab (Transtube) or Black topped		
	Microbiology (Charcoal) swab		
	For virology send the swab in a virus		1-4 days
	transport medium		1 1 days
Mumps IgG Antibody	Testing mumps immunity/past infection		5-7 days
	Clawad bland		
	Clotted blood		
Monkeypox PCR	Diagnosis of monkeypox virus	1 & 8	7 days
	Viral swab of vesicles and placed in viral		
	transport media		
Mumps IgM Antibody	Diagnosis of recent mumps		5-7 days
	Clotted blood		
	Clotted blood		
Mycobacteria	See TB (Mycobacterium tuberculosis /	2	
-	other Mycobacteria)		
Mycology culture	For skin, nail and hair clippings use black		2-4 weeks
,	card, Dermapaks or sterile universal.		
	For investigation of Candida infections in		2-4 days
	superficial wound/ENT sites, send a swab		



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	in Blue topped Microbiology swab (Transtube) or Black topped Microbiology (Charcoal) swab, request routine culture including Candida		
Mycology PCR	<ul> <li>For information on:</li> <li>Aspergillus antigen (Galactomannan)</li> <li>Aspergillus PCR</li> <li>Glucan (β-Dglucan)</li> <li>refer to individual tests in this table.</li> <li>For panfungal PCR/ 18s – contact the Consultant Microbiologist</li> </ul>		
Mycoplasma pneumoniae PCR	Respiratory sample (Sputum / BAL / NPA)	2	5-7 days
Mycoplasma pneumoniae IgM Antibody	Clotted blood		3-5 days
Nasal swab	Send a swab in Blue topped Microbiology swab (Transtube) or Black topped Microbiology (Charcoal) swab For virology, send a plastic shafted dacron swab in virus transport medium		2-4 days 3-5 days
Norovirus PCR	Only performed on unformed stools (Bristol stool chart 6 & 7) from in-patients (only performed on WUTH in-patients after Consultation with the Infection Control team)  Or after discussion with Consultant Microbiologist in Immunocompromised patients  Transfer 1 gram (large pea-size) portion of faeces, or 1-2 ml volume of liquid specimen, into a sterile universal container		24 hours  Urgent 4 hours from receipt
Parvovirus B19 IgG	Clotted blood		1-4 days



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Parvovirus B19 IgM	Clotted blood		1-4 days
Parvovirus B19 igivi	Clotted blood		1-4 days
Parvovirus B19 PCR	EDTA blood	2	1-4 days
	Clotted blood		
	Amniotic fluid		
Pertussis culture	Use a thin wired pernasal swab (pale blue		5 days
(whooping cough)	top) and transport immediately to the		
Diamet Fluid	laboratory for pertussis culture/PCR		O.F. days
Pleural Fluid	Culture and Sensitivity >1ml in a sterile universal container		2-5 days
	universal container		
	Tuberculosis culture >1ml in a sterile		6-8 weeks
	universal container		0-0 WCCK3
Pneumococcal	Clotted blood	2	2-3 weeks
Antibodies			
(Quantitative)			
Pneumococcal	>3ml Urine in a sterile universal		Same day
Antigen			as receipt
Droumoovotio iirovooii	Drongho alveder levere	2	2 E dovo
Pneumocystis jirovecii PCR	Broncho-alveolar lavage	2	3-5 days
FUN	Sputum (ideally induced)		
	Opatam (lacally madeca)		
	If no respiratory samples: EDTA Blood		
	Urgent Request must be discussed		Urgent
	with a Consultant Medical Microbiologist		24 hours
			from receipt
Polio Antibodies	Clotted blood	1	5-7 days
Danida I DNIA I III / DOD	EDTA Hand		F 7 -1
Proviral DNA HIVPCR	EDTA blood	1	5-7 days
Pus	Transfer into a sterile universal container		2-5days
			,
	If pus cannot be obtained then send a		5-7 days for
	swab in Blue topped Microbiology		extended
	swab (Transtube) or Black topped		culture
	Microbiology (Charcoal) swab – refer to		
	Wound and Ulcer Swabs		
Rabies	For any request for Rabies diagnosis,		
TADIOS	prevention or immunity testing contact		
	Consultant Microbiology		
	- Companies and the control of the c		
Respiratory PCR (full	PCR for:	2	1 day
panel)	Influenza A and B, Parainfluenza 1-4,		-
	Human Metapneumovirus, Adenovirus,		Urgent
Urgent screens	Respiratory Syncytial Virus,		Biofire



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performed in outbreak situations and by arrangement with Consultant Medical Microbiologist	Rhinovirus/Enterovirus, MERS, Coronavirus 229E, HKU1, NL63, OC43, SARS-CoV-2, Bordatella pertussis/parapertussis, Chlamydia pneumoniae, Mycoplasma pneumoniae  NB. Biofire not verified for immunosuppressed patients.  Nasopharyngeal aspirates and Broncho alveolar lavage (send in a sterile universal container)  Nose/Throat swabs in viral transport media (both swabs in same tube (can be processed from same sample as flu screen)  Swab of nasal secretions or throat swab, send plastic shafted Dacron or rayon swab in viral transport media (swab and media supplies as a pack)  Additional virus PCRs can be arranged by request through the Consultant Medical Microbiologists e.g. bocavirus.  Supplies of swabs and Viral Transport media can be obtained from Pathology Specimen Reception (In outbreak situations supplies may be placed in other locations)		24 hours from receipt
Respiratory Syncytial Virus (RSV) PCR	Refer to information for Influenza Virus PCR		
Rotavirus antigen	Detection of rotavirus in faeces. Transfer 1 gram (large pea-size) portion of faeces, or 1-2 ml volume of liquid specimen, into a sterile universal container		24 hours
Rickettsia Antibodies	Clotted blood	3	5-7 days
Rubella IgG	Immunity check (routine antenatal screening no longer routine) or past infection		2-5 days
	Clotted blood		



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Rubella IgM	IgM antibody: to diagnose recent acute infection in symptomatic or asymptomatic individuals  Clotted blood		2-5 days
Schistosoma serology	Clotted blood	6	5-7 days
Schistosoma detection (from urine)	It is preferable to obtain total urine collected over the time period between 10.00h and 14.00h. Alternatively, a 24h collection of terminal samples of urine may be obtained.		24 hours
Screening swabs and surface swabs	Send swab in Blue topped Microbiology swab (Transtube), or Black topped Microbiology (Charcoal) swab		2-4 days
Seminal fluid culture	Sterile universal container		2-4 days
Sexual Health Screening			
Chlamydia / Gonorrhoea PCR (CT/NG)	Samples from all requesters (excluding Wirral Sexual Health)	9	
	For investigation of <i>C.trachomatis</i> Infection in the eye, send a swab from the conjunctiva in VTM/Roche collection tube.		3-5 days
	For detection of CT/NG from the throat, vaginal, urethral & anorectal sites use a Roche Cobas <b>Un</b> i swab.		3-5 days
	For detection in urine first catch urine is required, optimally this should be collected in a Roche urine collection tube.		
	Self-taken HVS in a Roche Cobas <b>Un</b> i Swab.		
C	Not routinely available – contact Consultant Microbiologist for advice		
Trichomonas vaginalis (TV)		9	3-5 days
Mycoplasma genitalia			l .



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Sputum culture	Sputum from deep expectoration and not saliva is required. Send specimen in a 30ml sputum container or universal		2-4 days (5-7 days if fungal culture also required)
Strongyloides serology	Clotted blood	6	5-7 days
Syphilis serology	A combination of non-Treponema and specific Treponema antibody screening tests for Treponema pallidum  Clotted blood		1-4 days
Syphilis PCR	Virology swab in VTM: Ulcer Mouth Swab	2	3-5 days
Tetanus Antibodies (Quantitative)	Clotted blood	1	4 weeks
Throat swab	Send a swab in Blue topped Microbiology swab (Transtube), or Black topped Microbiology (Charcoal) swab		2-4 days
	For virology send the swab in virus transport medium (refer to respiratory PCR)		1-3 days
Tissue / bone /	Sterile universal container		2-5 days
cartilage and biopsies	If biopsy is small add 0.5ml of sterile saline to prevent it from drying out. Ensure there is NO formalin or other preservative in samples for culture: samples in formalin can still be used for bacterial, fungal and viral PCRs.		5-7 days for extended culture
G	(Depending on the nature of the tissue / bone / cartilage enrichment and extended culture maybe required which will take up to 7 days)		
TORCH Screen	Clotted blood		3-5 days
Toxocara Antibodies	Clotted blood	6	5-7 days



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Toxoplasma Antibodies	Clotted blood	7	2-4 days
Toxoplasma PCR	EDTA Blood Amniotic fluid Tissue	2	1-4 days
TB ( <i>Mycobacterium</i> tuberculosis) / other Mycobacteria	Recommended specimens are sputum, urine, pus or tissue. For sputum and urine send 3 early morning specimens taken on consecutive days	2	6-8 weeks Microscopy 2 days
	Blood culture bottles available to send out to wards for direct inoculation of blood or bone marrow for TB culture, please contact the Laboratory for special bottle (inoculate ONE bottle a day for 3 consecutive days)		6-8 weeks
Urethral swab	For the investigation of gonorrhoea use a swab (orange topped Microbiology swab) transport to the laboratory immediately.		2-4 days
	For detection of Chlamydia trachomatis and/or Neisseria gonorrhoeae by PCR refer to Sexual Health Screening		
	Do NOT order urethral swabs for MRSA culture (order MRSA screen and add urethra as the site)		
Urine	Collect mid-stream of urine in a red capped (boric acid) sterile universal container (>3ml)		
	Very small samples from paediatric patients only may be collected into a 20ml white capped sterile universal (white capped samples MUST be received in the lab within 4 hours of collection).		
O	Negative urine		24 hours
	Positive urine (1 organism isolated) Positive urine (2 organisms isolated)		2-4 days 4-6 days
	For detection of Chlamydia trachomatis and/or Neisseria gonorrhoeae by PCR refer to Sexual Health Screening		



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Urinary Legionella antigen & Urinary Pneumococcal Antigen	Collect mid-stream of urine in a sterile universal container (>3ml)		Same day as receipt
Varicella zoster IgG Antibodies	Varicella zoster IgG. Positive result indicates infection with VZV at some time or vaccination  Antibody 'negative' high risk groups with exposure <10 days can be offered human zoster immunoglobulin for pregnant women or immunocompromised patients if level less than 150iu/l.  Clotted blood		2-4 days  Urgent 1-3 hours from receipt (provisional result only)
Varicella zoster IgM Antibodies	Clotted blood	),	3-5 days
Varicella zoster PCR	EDTA blood CSF Lesions Vesicle fluid	2	2-4 days
VDRL	Refer to Syphilis serology		
Vesicles, ulcers and genital lesions	Send a swab in virus transport medium for PCR	2	2-4 days
Wound and ulcer swabs	Send a swab in Blue topped Microbiology swab (Transtube), or Black topped Microbiology (Charcoal) swab		2-4 days
Yersinia antibody tests (reference lab test- availability limited so needs discussion with Consultant Microbiologist)	Clotted blood	1	5-7 days

Specimens should be transported to the Laboratory as soon as possible after they are taken, even overnight so they can be placed in the correct storage conditions

#### \*Reference Lab Referrals

Tests are referred to a number of outside Laboratories. These are listed below:

- 1. Public Health England, 61 Colindale Avenue, London NW9 5HT
- 2. Public Health England, Manchester Laboratory, Manchester Royal Infirmary, Oxford Road, Manchester. M13 9WL



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- 3. Public Health England, RIPL Porton Down, Salisbury, Wiltshire. SP4 0JG
- Public Virology and Mycology Reference Laboratory, National Infection Services, Public Health England South West Laboratory, Science Quarter, Southmead Hospital, Bristol, BS10 5NB
- 5. National Public Health Service for Wales, Anaerobe Reference Laboratory, NPHS Microbiology Cardiff, University Hospital of Wales, Cardiff. CF14 4XW
- 6. Liverpool School of Tropical Medicine, Pembroke Place, Liverpool L3 5QA
- 7. Toxoplasma Reference Laboratory, Department of Microbiology, Singleton Hospital, Sgeti, Swansea SA2 8QA
- 8. Brucella Special Diagnostic Unit, Virology Department, Liverpool Clinical Laboratories, Mount Vernon Street Liverpool L7 8YE
- Virology Department, Liverpool Clinical Laboratories, Mount Vernon Street Liverpool L7 8YE
- 10. Mycology Reference Centre Manchester, 2nd Floor Laboratory, Education and Research Centre, Wythenshawe Hospital, Southmoor Road, Manchester. M23 9LT

# 11.0 KEY FACTORS WHICH AFFECT THE PERFORMANCE AND OR RESULT OF A MICROBIOLOGY TEST

- The technical competency, bias and experience of the staff performing the test.
- The patient sample, how it is taken, stored and transported to the laboratory.
- The homogeneity of the patient sample i.e., is there an even distribution of micro-organisms within the sample?
- Dilutions, how they are performed, what volume is used and how accurate is the equipment used to perform the dilution.
- Media and reagents, if they are not stored correctly, used in the correct way,
   expired and are not sensitive and specific enough they will have a detrimental effect on the result.
- Inoculation of media, volume of inoculum, media selection and spreading of inoculum will affect the result.
- Incubation conditions such as duration, temperature and humidity.



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- Reading and interpretation of results.
- The uncertainty of measurement (UoM) is a quantitative indication of the quality of the result and how reliable and reproducible it is. Reports for UoM are generated every 12 months. All UoM reports are reviewed by the Consultant Microbiologists for clinical impact. If the reports indicate the results may have a clinical impact the users will be informed accordingly. Users can request to view the UoM information.
- If a change is made to an examination procedure which could affect the interpretation of a result, this will be communicated to users.

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# 11.0 CONTAINERS APPROPRIATE FOR TRANSPORT OF SPECIMENS FOR MICROBIOLOGICAL INVESTIGATIONS

SPECIMEN	CONTAINERS
Clotted blood for serology:	Wirral: 4ml OCHRE capped, clear plastic blood tube
	Chester: 8ml clotted blood (Red or Gold top) clear plastic tube
Blood for PCR (Viral DNA/RNA)	Wirral: 4ml LAVENDER capped clear plastic EDTA blood tube.
	Chester: 8ml EDTA (Purple top)
Blood Cultures	Wirral: Green (O <sub>2</sub> ) and purple (ANO <sub>2</sub> ) bottles
	Chester: Blue (O <sub>2</sub> ) and purple (ANO <sub>2</sub> ) bottles
	Paediatric (both sites): Single yellow bottle
Urine for MC&S and urinary antigens	Red capped boric acid container
	20ml universal bottle (white cap) – Paediatric urine only where a small volume is collected
Body fluids eg joint fluid, CSF, pus	20ml universal bottle (white cap)
For faeces, pus, tissue / bone / cartilage and other	50ml wide-mouth container (Wirral)
semisolid specimens	Blue 30ml container with spoon (Chester)
For the collection and transport of specimens, when Chlamydia trachomatis is suspected	All requestors including Wirral Sexual Health Roche Cobas Uni Swab/urine collection tube
For the aerobic collection of small amounts of fluids, or exudates	Standard cotton wool-tipped rigid stem swab (blue top) & transport medium or Standard cotton wool-tipped rigid stem swab (black top) & charcoal transport medium
For sampling ear, nose or throat, or urethral discharge	Special cotton wool-tipped fine rigid wire swab (orange top) & transport medium
For sampling post-nasal space	Special cotton wood-tipped fine flexible wire swab (sky blue top)
For the anaerobic collection of pus, or exudates	Sterile universal container
For the collection and transport of swabs for virus tissue culture/PCR	Use viral collection kit (2 female swabs and viral transport media)
For the collection and transport of urine for cytomegalovirus (CMV) tissue culture	Early morning urine in 20ml universal bottle (white cap)

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### 12.0 REFERENCE RANGES

SPECIMEN	REFERENCE RANGE	COMMENT
URINE	White Blood cells <10x10 <sup>6</sup> /L Red Blood cells <17x10 <sup>6</sup> /L	Normal reference range WBCs <10 RBCs <17 (x10 <sup>6</sup> /L) Pyuria is defined as WBC >10 x10 <sup>6</sup> /L WBC >100 x10 <sup>6</sup> /L is considered more suggestive of infection The urinanalyser does not reliably detect or
		measure microscopic haematuria. Please correlate clinically.
CSF	Neona	tes/Newborns:
	White Blood cells Neonates (<28 days old including pre-term) 0 - 30 (x10 <sup>6</sup> /L)	Normal reference range Preterm <28 days old - WBC 0-30 (x10*6/L)
	Red Blood cells 0 - 675 cells x 10 <sup>6</sup> /L	(A WBC:RBC ratio of 1:500 to 1:1000 is suggestive of a traumatic tap)
	Childr	en and adults:
	White Blood cells Infants 1-12 mths 0 - 15 (x10 <sup>6</sup> /L)	Normal reference range Infants 1-12 months WBCs 0-15 (x10 <sup>6</sup> /L)
	Children/Adults (1+ yrs) 0 - 5 (x10^6/L)	Normal reference range Children/Adults (1+ yrs) WBCs 0-5 (x10 <sup>6</sup> /L)
	Red Blood Cells 0 - 10 cells x 10 <sup>6</sup> /L	(A WBC:RBC ratio of 1:500 to 1:1000 is suggestive of a traumatic tap.)
Anti Strontolysin O	<b>Adult:</b> 0 – 200 IU/MI	
Streptolysin-O antibody	Children <4yrs: 0-100 IU/MI	
β-D-Glucan	Measurement range 6-500-pg/ml	≥6.00 ≤6.99 pg/ml - Indeterminate (I)
	<6 pg/ml Negative (N)	
CO.	≥7 pg/ml Positive <b>(P)</b>	



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Hepatitis B immunity (anti-HBs)	An antibody level below 10m IU/ml is classified as non-immune (a non-response to vaccine).
	Responders with anti-HBs levels of 10 to 100m IU/ml should receive one additional dose of vaccine at that time.
	Responders with anti-HBs levels greater than or equal to 100m IU/ml do not require any further primary

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#### **13.0 APPENDIX 1**

#### Interpretation of Clostridium difficile testing results

CWMS microbiology laboratory combines two different tests to optimize sensitivity and specificity of *C. difficile* testing. The polymerase chain reaction (PCR) test (detects the genes encoding the *C. difficile* toxins) is followed by a toxin EIA test.

If the PCR is positive, it implies that the patient has *C difficile* in their gastrointestinal tract, with the capability to produce toxins. However, this method cannot determine if the *C. difficile* strain actually produces toxins. The EIA toxin test is suitable for the detection of the *C. difficile* toxins in the stool specimens. Please note, according to National Guidance the *C. difficile* toxin EIA test is not suitable as a stand- alone test for the diagnosis of *C. difficile* infection because of low sensitivity (that results in a high rate of false negatives).

Reporting and interpretation of *C. difficile* results:

#### 1. Toxin gene DETECTED/toxin production DETECTED

Both the PCR and toxin EIA tests are positive. In symptomatic patients this result confirms the diagnosis of *C. difficile* infection. Appropriate antibiotic treatment and infection control precautions are required.

This will be reported as:

C.difficile toxin gene detected by PCR

C.difficile toxin production detected by EIA

Positive for C.difficile toxin, likely to be significant in the appropriate clinical context.

#### 2. Toxin gene DETECTED/toxin production NOT detected

The PCR test is positive, that means the patient carries toxigenic *C.difficile* strains in the gastrointestinal tract. However, the EIA toxin test remained negative.

The patient might be an asymptomatic carrier (in which case the toxin test is true negative), or the patient has toxigenic *C.difficile* infection with a false negative EIA test.

Clinical review and correlation are required. If the patient is symptomatic, appropriate treatment and infection control precautions are required.

This will be reported as:

C.difficile toxin gene detected by PCR

C.difficile toxin production NOT detected by EIA

Interpretation: C.difficile bacteria detected. Potential for

C.difficile toxin to be produced but not detectable at

Present. Clinical correlation required to determine whether

C.difficile infection causing symptoms or C.difficile

colonisation with another cause of the symptoms.

#### 3. Clostridium difficile NOT detected

The PCR test is negative. Alternative diagnosis should be considered. If high suspicion of C. difficile infection, sending a repeat specimen can be considered.

This will be reported as: Toxigenic Clostridioides difficile NOT detected