

UK Standards for Microbiology Investigations



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Acknowledgments

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UK SMIs are produced in association with:

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Amendment table

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Any alterations to this document should be controlled in accordance with the local document control process.

Amendment number/date	x/dd.mm.yy				
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Reviews can be extended up to 5 years where appropriate					
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Investigation of Nasal and Paranasal Sinus Samples

1 General information

View general information related to UK SMIs.

2 Scientific information

View scientific information related to UK SMIs.

3 Scope of document

This UK Standards for Microbiology Investigations (UK SMI) document decorbes the examination of sinus aspirate and associated specimens for the detection and recovery of the organisms that cause the various forms of rhinosinusities. This document does not cover the investigation of nasal and paranasal situal samples for viral or allergic and toxin origins.

Other diagnostic techniques such as computed tomography (()) scans are commonly employed by healthcare professional for the diagnosis of repositive sinusities and should be considered alongside the microbial methods mentioned in this document.

Please refer to <u>UK SMI B 29 - Investigation of Specificens for Screening for MRSA</u> for information on screening for MRSA nasal carriage

Please note the following:

This document does not focus on the identification of organisms causing rhinosinusitis. The identification section is this document only provides information on the identification level of organisms which is linked to the reporting process. For additional details, please refer to the appropriate identification documents mentioned in the dedicated section.

This document specifically addresses samples sent to clinical laboratories for diagnosis, whether they are from primary or secondary (hospital) healthcare. Most cases of rhinosinusitis are typically diagnosed and managed in primary healthcare settings without the occessity of sending samples to clinical laboratories. Also, most cases are uncomplicated and tend to resolve on their own without antimicrobial prescription. For more information, refer to the NICE guideline on <u>Sinusitis (acute):</u> antimicrobial prescribing and to their website for information on the management of acute an conronic rhinosinusitis and prescribing information.

The dyancement of molecular phylogenetic analysis has greatly influenced the taxonomy of microorganisms, especially fungi. This has resulted in the reclassification and renaming of many species. For the purpose of this document, both the previous and current nomenclature of reclassified species or species with updated nomenclature will be mentioned as required.

Many species formerly part of the genus Candida now belong to a number of other genera. When referring to Candida collectively the term 'Candida and associated ascomycetous yeast species' will be used.

This UK SMI should be used in conjunction with other relevant UK SMIs.

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Introduction Δ

4.1 Rhinosinusitis

Rhinosinusitis refers to inflammation in the nasal mucosa and one or more of the paranasal sinuses: maxillary, ethmoid, frontal and sphenoid, with the maxillary being the commonest sinus to get infected (1). It can result from viral, bacterial, or fungal infections (1.2). Clinical presentations of rhinosinusitis are diverse and can overlap with other conditions such as hay fever. Symptoms include nasal congestion and discharge, facial pain, pressure or fullness, headaches, and fatigue. Factors that predispose an individual to rhinosinusitis include impaired mucociliary function obstruction of the sinus entrance (e.g., by nasotracheal intubation or by much sal oedema as a result of viral infection) and defects in the immune system (3) The sinus cavities are usually sterile or may contain small numbers of bacteria that are continuously removed by the mucociliary system.

Rhinosinusitis aspiration is generally the preferred method for specimen collection as it allows more targeted sampling and reduces risk of contamination by upper respiratory tract flora (1,4). Specimens should be collected by Ear, Nose and Throat (ENT) surgeons and obtained through rigid endoscopy councture and careful aspiration of the sinus cavity avoiding contamination by opper respiratory tract flora.

In the case of suspected invasive fungal rhinosinustics, a biopsy sample may also be obtained for direct microscopic examination prior to culture to identify the presence of fungal elements (5.6). 1 Mai

4.1.1 Acute rhinosinusitis

Acute rhinosinusitis is often suspected if the symptoms meet clinical criteria and deteriorate after 5 days or persisteeyond 10 days (less than 12 weeks). The aetiology of community acquired infections can be viral, bacterial, mixed (viral and bacterial), or occasionally fungal (partice river in immunosuppressed patients), with viral upper respiratory tract infections being the commonest cause of acute rhinosinusitis.

For acute rhinosinusities, routine culture and antibiotic prescription is not recommended as acute rhinosing this often resolves on its own without the need for antibiotics (4,7).

Culture is selectively obtained in individuals at high risk of complications or antibiotic resistance of tibiotic prescription is often reserved for patients with persistent or worsening symptoms or complications of acute rhinosinusitis (7).

Community rhinosinusitis

The most common bacteria isolated from cases of acute community acquired sinusitis are Streptococcus pneumoniae, non-typeable Haemophilus influenzae (NTHi) and Moraxella catarrhalis which is more prevalent in children than adults (1.8). Other less common organisms isolated are streptococci of the "anginosus" group (Streptococcus anginosus, Streptococcus constellatus and Streptococcus intermedius), group A streptococcus, other α -haemolytic streptococci, Staphylococcus aureus, and anaerobic bacteria (which are infrequent in children) (1,9).

Nosocomial rhinosinusitis

Nosocomial sinusitis is often a complication in endotracheal intubation and mechanical ventilation and often shows no clinical signs of infection (10). The causative organisms can vary, and infections are often polymicrobial (11). Pseudomonas aeruginosa and other Gram-negative rods commonly cause nosocomial rhinosinusitis in intensive care and immunocompromised patients (1,12). Similar pathogens and polymicrobial infections have been identified in children with more anaerobes being isolated (13). Acute fungal rhinosinusitis caused by Aspergillus or Mucorales spp. can occur in immunosuppressed patients, such as haematology patients undergoing chemotherapy, allogeneic or solid-organ transplantation recipients and patients with poorly controlled diabetes.

Nosocomial infections are often underestimated and difficult to diagnose in intensive care patients, therefore close collaboration among physicians, ENT surger microbiologists and histopathologists is necessary to reach a diagnosis

4.1.2 Chronic rhinosinusitis

24 MS Chronic rhinosinusitis is a long-term inflammation of the sinuses that last for longer than 12 weeks without complete resolution. The inflammation can be triggered by various factors including allergies, anatomical abnormaties, or environmental irritants. It may also be a feature of some congenital immung ficiency syndromes and disorders of mucociliary function, although most of tents do not have these conditions.

Chronic rhinosinusitis can also persist in some patients who have undergone unsuccessful surgery. Infections may contribute to or worsen the condition but cannot fully explain the persistent inflammation while complexity makes chronic sinusitis more multifaceted than a simple infectious origin.

Chronic sinusitis is clinically sub-categorised by the presence or absence of nasal polyps (CRSwNP or CRSsNP respectively). Further research and understanding of chronic sinusitis have led to the proposal of additional categorisation models to enhance the accuracy of cognosis and management of different subgroups of patients (14-16).

The microbiology of monic rhinosinusitis differs significantly from that of acute rhinosinusitis, and commonly caused by anaerobes, Gram-negative bacteria, Staphylococc Saureus, and fungi (usually Aspergillus spp. and occasionally other moulds). The persistence of infection or extension of unresolved acute rhinosinusitis can lead to a shift in the types of bacteria present from aerobic to anaerobic bacteria including Pseudomonas aeruginosa, Enterobacterales, Peptostreptococcus species, Propionibacterium species, Fusobacterium species, Prevotella species and other anaerobic Gram-negative bacteria.

Chronic sinusitis can lead to serious and life-threatening complications with the most common being orbital infections (17-19). Intracranial infections are less common but may cause significant morbidity and mortality. Another rare complication is osteomyelitis (see UK SMI B 42 - Investigation of Bone), involving the frontal bone (Pott's puffy tumour). Staphylococcus aureus and anaerobes are the predominant isolates from such cases and are also recovered from children with severe

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rhinosinusitis symptoms requiring surgical intervention, or with protracted rhinosinusitis (lasting over one year) (20).

4.1.3 Fungal rhinosinusitis

Fungal rhinosinusitis can be acute or chronic and is categorised into non-invasive and invasive fungal rhinosinusitis depending on the extent of fungal involvement in the sinuses and the severity of the infection. Non-invasive fungal rhinosinusitis may take the form of a fungus ball in the sinus, saprophytic fungal rhinosinusitis, or allergic fungal rhinosinusitis (21-23). Invasive fungal rhinosinusitis can be either acute or chronic and may form granulomas within the sinus cavities. Granulomas invasive sinusitis may be confused with Granulomatosis with polyangiitis (formerly known as Wegener's granulomatosis) or squamous cell carcinoma (21). Therefore, commination of tissue rather than pus is important in fungal rhinosinusitis and close comperation among the surgeon, microbiologist and histopathologist is also necessary (5,21). Acute invasive rhinosinusitis can spread rapidly from the involved structures and is to be regarded as a medical emergency. Aggressive surgical debridement is often required in addition to systematic antifungal therapy and treatment of the underlying cause.

Fungal rhinosinusitis is predominantly caused by moulds with *Aspergillus* species being the most common pathogens. Other moulds that are less commonly encountered include Mucor and Rhizopus which are associated with the fatal invasive fungal infection, mucormycosis (24,25). The exception to this are thermally dimorphic fungi such as *Sporothrix schenckii* which are the sausative agents of endemic mycoses. These exist as tissue invasive yeast at human body temperature and as moulds in the environment (26). They are live ted by geographical distribution and rare in the UK.

Community-acquired chronic fungal rhmosinusitis is a relatively common problem in some tropical and subtropical comprises which can in some instances lead to invasive disease, e.g., in Africa and Indicand imported cases may be encountered (25). The commonest cause overall is spergillus flavus, but other fungi should be considered.

It is important to take inconsideration the country of origin and travel history of patients in suspected cases of fungal rhinosinusitis to help determine the causative agent of infection. Fono-orbital cerebral mucormycosis, which became more prevalent in Indianaring COVID-19 pandemic, highlights the importance of such consideration, in diagnosis and treatment planning (27)

5 Gafety considerations

The section covers specific safety considerations (28-49) related to this UK SMI, and should be read in conjunction with the general <u>safety considerations</u>.

5.1 Specimen Collection, Transport and Storage:

Use aseptic technique.

Collect all specimens before antimicrobial or antifungal therapy where possible.

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Collect specimens in appropriate CE marked leak-proof containers and transport in sealed plastic bags.

Compliance with postal, transport and storage regulations is essential.

5.2 Specimen Handling, Processing and Examination:

The majority of diagnostic work can be conducted at Containment Level 2. However, specific procedures involving mycology work and certain hazard group 2 bacterial isolates should be conducted within a microbiology safety cabinet.

When Hazard Group 3 organisms are suspected, all specimens must be processed in a microbiology safety cabinet under full containment level 3 conditions. General containment level 3 procedures are also recommended for the examination of cultures that may contain dimorphic fungi and other pathogenic fungi. Sealed containers such as screw-capped bottles should be used for culture. Plates are not contained.

Any laboratory procedures that give rise to infectious aerosols wist be conducted in a microbiological safety cabinet.

Centrifugation must be carried out in sealed buckets which are subsequently opened in a microbiological safety cabinet.

Specimen containers must also be placed in a solution holder.

Refer to current guidance on the safe handling of all organisms documented in this UK SMI.

The above guidance should be supplemented with local COSHH and risk assessments.

6 Pre-laboratory processes (pre analytical stage)

6.1 Specimer Sype:

Antral washout shus aspirate, sinus washout, and tissue.

Please note that nose swabs should be used for <u>detection of MRSA nasal carriage</u> and are not a suitable sample type for the diagnosis of rhinosinusitis.

Note And one of the sample.

The choice of specimen is influenced by the patients' clinical details and the investigation aim. For example, sinus aspiration may be sufficient for the diagnosis of bacterial rhinosinusitis while additional biopsy may be required for the identification of fungal structure and more detailed analysis of tissue changes.

6.2 Specimen collection and handling:

For safety considerations refer to Section 5.

Collect specimens before antimicrobial therapy where possible.

Collect specimens other than swabs into appropriate containers and place in sealed plastic bags.

The washout or swab specimen will be collected by a specialist ENT surgeon

Ideally, a minimum volume of 1mL for washouts is required to ensure adequate sensitivity. One swab for other conditions.

Numbers and frequency of specimen collection are dependent on clinical explicition of patient.

NO

6.3 Specimen transport and storage:

Specimens should be transported and processed as soon as possible.

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

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

Samples should be kept at room temperature and processed immediately. If processing is delayed, refrigeration is preferable to storage at ambient temperature.

7 Laboratory processes (analytical stage)

7.1 Specimen processing:

For safety considerations ever to Section 5.

Standard

Non-mucoid sinus antral washouts are processed as follows:

- Centrifuse specimen (for antral washouts), unless very mucoid, at 1200 x g for 10 montes
- A grant most of the supernatant, leaving approximately 0.5mL
- Resuspend the centrifuged deposit in the remaining fluid
- Carry out microscopy and culture

Mucoid specimens are processed by digestion as follows:

- Carry out microscopy
- Add equal volume of a 0.1% solution of N-acetyl cysteine to specimen
- Agitate gently for approximately 10 seconds

Bacteriology | B 05 | Issue number: dl+ | Issue date: dd.mm.yy | Page: 10 of 26 UK Standards for Microbiology Investigations | Issued by the Standards Unit, UK Health Security Agency Incubation at 35-37°C for 15 minutes followed by gentle agitation for approximately 15 seconds will assist homogenisation

Note: do not exceed 20 minutes of incubation to avoid overprocessing the sample.

Inoculate plates

7.2 Microscopy

Refer to UK SMI TP 39 – Staining procedures

For information on technical limitations refer to scientific information.

Direct microscopic examination of fresh or stained specimens can provide diagnostic information on the presence of fungal structures as culture reference may not be available for a few days. This is particularly important for the prompt administration of anti-fungal therapy in immunocompromised patients. However, the method is insensitive and negative results do not rule out a fungal infection as may be the case in the early stages of the infection.

Standard

For mucoid specimens:

suc Using a sterile loop select the most purulent or bloop stained portion of specimen and make a thin smear on a clean microscope slide Kram staining.

For non-mucoid specimens

Using a sterile pipette place one drop of contributed deposit (see section 6.1.2) or neat specimen on to a clean microscope stide. Spread this with a sterile loop to make a thin smear for Gram staining.

Note: If fungal infection is suspected or seen in the Gram stain carry out the supplementary.

Supplementary

Using a sterile pipette place one drop of centrifuged deposit (see section 6.1.2) or neat specimen on a clean icroscope slide.

Examine at x 10 and x 40 magnification using potassium hydroxide (KOH) or enhanced with alcofluor white or blankophor white staining for fungal hyphae.



Using a sterile loop inoculate each agar plate with centrifuged deposit (see UK SMI Q 5 - Inoculation of Culture Media for Bacteriology).

For fungal culture on Sabouraud slopes use a pastette to place 2-3 drops of deposit onto the agar.

Table 1: Culture media, conditions, and organisms



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Clinical details/	Specimen Supplen media	Supplementary	Incubation			Cultures	T
conditions		media	Temperature °C	Atmosphere	Time	read A	Target organism(s)
Chronic rhinosinusitis or Rhinosinusitis in immunocompromised Patients ^b	Antral washout/ Sinus aspirate/ Sinus washout/ Tissue ^c	Sabouraud's dextrose agar⁴	30 to 37 ^e	Air and	Parto 7 Cayst	Greater than 40 hrs and at 5 to 7 days ^f	Moulds ^g
a may include either a bacitracin 10-unit disc or bacitracin incorporated in the agar. When bacitracin is incorporated into the plate a separate blood agar plate incubated in 5 to 10% CO2 will need to be put up to detect <i>M. catarrhalis</i> and <i>S. pneumoniae</i> .							
b immunocompromised patients groups include haematology, oncology, diabetes (uncontrolled), neutropenic (other)							
c when testing tissue biopsies, specimens should not be overly plocessed (e.g., crushed) as this may damage hyphal elements and minimise the chances for isolating the fungus							
d supplemented with chloramphenicol or gentamicin; chropsenic media may be useful for identifying mixed fungal infections.							
e in case of suspected mucormycosis or observation of phae of Mucorales in direct microscopy, it is recommended to incubate the cultures at two separate temperatures – 30 °C and 30°C to increase the yield.							
f moulds are the main fungal pathogens for rhino inusitis whilst yeast growth normally represents colonisation. Therefore, extended incubation is advocated for a minimum of 5 • Days, for all surgical samples and for the investigation of fungal rhinosinusitis in high-risk patients. Plates should be read after 40 hours and at 5 - 7 days. Some fungal pathogens may require extended incubation up to 14 days. If based on travel history endemic mycos a uch as histoplasmosis is a possibility, samples should be processed in containment level 3 and all yeasts identified to species level. g differentiation between yeast and hamentous forms may require microscopic examination. Wet mounts or stain with lactophenol cotton blue (LPCB) should be used.							

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For fungal culture, one Sabouraud dextrose agar with chloramphenicol (SABC) plate should be used per sample and streaked as per routine and standard bacteriology practice. However, increasing the number of plates will increase the sensitivity. It is highly recommended that SABS plates be sealed with gas-permeable tape or alternatively placed inside a sealable plastic bag during incubation to avoid cross contamination. Incubation of SABC plates in 'automated incubation and imaging' modules may lead to fundation of modules and other cultures. No fungal isolate should be dismissed as a 'contaminant' without full identification. If microscopy is suggestive of organisms not listed in the target list additional and/or other media may be required.

Laboratory should follow local protocols or manufacturer's instructions for optimal incubation conductors

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Consultation between T Way 2024 and 24

7.4 Identification

Refer to individual UK SMIs for organism identification.

Target organism	Identification level					
Peptostreptococcus species	"anaerobes" level					
Propionibacterium species	"anaerobes" level					
Fusobacterium species	"anaerobes" level					
Prevotella species	"anaerobes" level					
<u>β-haemolytic streptococci</u>	Lancefield group level					
Enterobacteriaceae	species level					
Fungi*	species level (if clinically significant)					
<u>H. influenzae</u>	species level					
<u>M. catarrhalis</u>	species level					
Pseudomonas species	species level					
<u>S. aureus</u>	species le le					
<u>S. anginosus</u>	S. anginosus group level					
<u>S. pneumoniae</u>	species level					

* Moulds are more common associated with rhinosinusitis.

Note: Any organism onsidered to be a contaminant may not require identification to species level. Organisms may be identified further if clinically or epidemiologically indicated.

7.5 Motecular assays

Molecular methods such as Nucleic Acid Amplification Test (NAAT) and fluorescence in situ hybridization have been developed for the rapid detection of fungal species directly from patient specimen. These assays allow for the timely diagnosis of invasive fungal rhinosinusitis from tissue samples and subsequently the prompt initiation of antifungal therapy. This is crucial due to the high risk of complications and mortality associated with these types of infections in immunocompromised and diabetic patients. In addition, molecular methods can help overcome some of the challenges encountered with culture-based methods such as false negative results and the identification of rare fungal species (50,51).

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There are numerous commercially available assays that have been developed for the detection of fungal organisms ranging from pan fungal to pathogen specific (e.g., Aspergillus, Mucorales) assays, with pathogen specific assays having higher sensitivity and faster turnaround time. The quality of these assays is largely dependent on the analytical range of detection provided by the specific assay, type and volume of specimen, the DNA fungal extraction method and automation of the process to increase sensitivity. Currently, the validation of NAAT for the diagnosis of fungal rhinosinusitis is relatively limited and it is essential that these assays are validated for the specimen type before their use in laboratories.

Despite the advancement in molecular methods, they are not routinely used for detection of fungal rhinosinusitis and have not yet replaced culture-based methods in clinical laboratories. These methods would often be used in conjunction with culturebased methods as appropriate or utilised largely by reference laboratories. Where fungal elements are visualized in specimens but are culture negative molecular testing may be a useful adjunct test to provide identification.

7.6 Antigen/antibody testing

and Antigen/antibody tests have many limitations and are not regularly used as diagnostic tools for rhinosinusitis, including invasive fungal (hinosinusitis. Factors that can influence the performance of these assays include variation in sensitivity and specificity depending on the clinical setting e., underlying conditions and immunosuppression as well as false positive results due to cross-reactivity e.g., individuals with yeast colonisation (52-53

Furthermore, antibody tests have inited applicability in the diagnosis of invasive fungal rhinosinusitis, because whe reduced or delayed antibody production in immunocompromised individual

ory processes (post analytical 8

- Reporting microscopy

Report microscopy results as:

Gram's stain

- 1. Report presence of WBCs.
- 2. Report if organisms detected.

Note: The presence of yeast cells e.g., *Candida* is very rare and usually a reflection of oropharyngeal colonisation. In such cases further histopathological evidence is required.

Fungal stain

- 1. Report presence or absence of fungal elements.
- 2. Differentiate between yeasts and filamentous fungi (moulds).
- 3. Where possible provide a description of the filamentous fungi/element observed.

Notes:

- The presence of fungal structures in biopsy specimens from deep tissues should be reported as clear/proven evidence of fungal infection.
- The presence of broad, aseptate or pauci-septate hyphae with wide gle branching is consistent with Mucorales. The presence of regularly septate hyphae with 45° branching is consistent with Aspergillus species but could represent other hyaline fungi such as Scedosporium species

Reports simply stating fungal elements seen with no differentiation, are of limited clinical utility and should be avoided.

cinical utility and should be avoided.
8.1.2 Microscopy reporting time
Interim or preliminary results should be issued effection of clinically significant results as soon as growth is detected unless specific alternative arrangements have been made with the requestors.

In immunocompromised patients or when fungal investigation is specifically requested, microscopy positive fungal results indicating presence of filamentous hyphae indicative of mucoraceous mould members of Mucorales) or Aspergillus species should be immediately commutated to the consultant looking after the patient or an infection consultant liaising with the clinical teams.

Urgent results should be telephoned or transmitted electronically in accordance with local policies.

Final written or nputer-generated reports should follow preliminary and verbal reports as soon as possible.

8.2.1 Reporting Culture

Bacterial Culture

- 1. Clinically significant organisms with antimicrobial susceptibility results
- 2. No growth of clinically significant organisms*
- 3. No growth

* Identification should not be reported for organisms of no clinical significance.

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Fungal culture

- 1. Yeasts should be reported along with an indication of growth quantity of scantly/light, moderate or heavy to allow for interpretation of significance.
- 2. Isolation of any filamentous fungi should be reported, irrespective of burden.
- 3. No fungal growth.
- 4. Fungal growth may be reported as negative after 48 hours incubation although cultures will continue to be incubated up to 5 7 days and extended culture (up to 14 days may be required where fungal rhinosinusitis is specifically suspected. In the event of fungal growth, a further report will be issued.

Note: The presence of fungi should be documented even when a fungal catter is overgrown by chloramphenicol-resistant Gram-negative bacterial (e.g., Pseudomonas spp.). This should be noted in the result and not reported as 'fungi not isolated'.

All clinically significant fungal isolates should be identified to species level (for yeast species, level identification is essential in recurrent or recalcition infections).

8.2.2 Culture reporting time

Interim or preliminary results should be issued on detection of clinically significant isolates as soon as growth is detected unless specific alternative arrangements have been made with the requestors.

Urgent results should be telephoned or transmitted electronically in accordance with local policies.

Final written or computer-generated reports should follow preliminary and verbal reports as soon as possible.

See appropriate UK SMIs for scoplementary investigations.

8.3 Reporting other tests including molecular testing

As newer and more ovel methods are becoming available, their validation and reporting would be as per local laboratory testing protocol.

9 Antimicrobial susceptibility testing

For interpretation of susceptibility testing results, laboratories should test and interpret according to the EUCAST breakpoint, refer to <u>EUCAST guidelines for breakpoint</u> <u>information</u>.

Alternatively, the Clinical and Laboratory Standards Institute (CLSI) method along with the corresponding CLSI breakpoints can be used: <u>Susceptibility Testing</u> <u>Subcommittees (clsi.org)</u>.

Alternatively, isolates can be sent to an appropriate specialist or reference laboratory.

Antifungal susceptibility testing should be performed for fungal rhinosinusitis, when a culture is available.

9.1 Reporting of antimicrobial susceptibility testing

Report susceptibilities as clinically indicated. Prudent use of antimic is according to local and national protocols is recommended.

10 Referral to reference laboratories

In case of sending away isolates to reference or specialist testing laboratories for processing, ensure that the specimen is placed in the appropriate package and transported accordingly. Follow local regulations and instructions provided by the reference or specialist testing laboratories for sending isolates.

Contact the appropriate reference laborator (refer to the links provided below) for information on the tests available, turnaround times, transport procedure and any other requirements for sample subminision.





Algorithm: Investigation of Nasal and Paranasal Sinus Samples

Please see the document for a gorthm details. If microscopy is suggestive of organisms not listed in target list, additional and/or other media may be required. In addition, if longal elements are seen but the culture is negative, molecular identification may be useful.

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An explanation of the reference assessment used is available in the <u>scientific</u> information section on the UK SMI website.

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