

**Sample, Report**

Date Of Birth: 07/02/1980 (35 yrs)  
 Gender: Female  
 Patient Id:  
 Patient Location:

**Ordering Provider**

Ronald McGlennen MD  
 7400 Flying Cloud Drive  
 Eden Prairie, MN 55344  
 855-672-5362

**Sample Information**

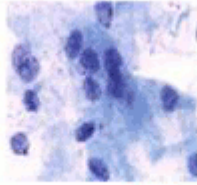
Specimen#: 89499693  
 Accession#: 201509-03071  
 Specimen: Oral Rinse  
 Collected: 09/16/2015 09:05  
 Received: 09/18/2015 08:18  
 Reported: 09/20/2015 09:25

**Reason for Testing:** Suspicion of oropharyngeal thrush  
**Related info:** Not Provided  
**Patient History:** Not Provided

**Lesion Size:** Not Provided  
**Lesion Color:** Not Provided  
**Lesion Location(s):** Not Provided

**MOLECULAR IDENTIFICATION OF CANDIDA SPECIES IN THE OROPHARYNX**

Test Results	
Candida Species	Negative

<p><b>Signs &amp; Symptoms of Oral Candidiasis</b></p> <ul style="list-style-type: none"> <li>• Often no symptoms</li> <li>• "Burning mouth syndrome"</li> <li>• Metallic or acidic or salty taste</li> </ul>	 <p>Candida species</p>	<p><b>Causes</b></p> <ul style="list-style-type: none"> <li>• Various Candida species, most often C. albicans</li> <li>• Underlying systemic disease</li> <li>• Immunosuppression</li> </ul>
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**Interpretation:**

This sample is negative for Candida species DNA. See comments.

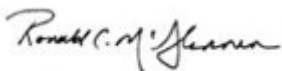
**Comments:**

- **Significance:** Oral candidiasis (Oral thrush) is caused by a candida fungus that can infect the mouth. Oral thrush causes creamy white lesions, usually on the tongue or inner cheeks and may spread to the roof of mouth, gums, tonsils, or the back of the throat. It is not a type of infection that can be passed on to others.
- **Risk:** Oral thrush most commonly affects people who wear dentures. People who have difficulties keeping their mouth clean, people with diabetes and those who take steroids are also at a higher risk of developing the condition. Some antibiotics may cause thrush. Certain antibiotics encourage the infection to recur, especially if taken over a long period of time. Very rarely, oral thrush may be one of the early signs of HIV.
- **Consider:** The current negative result does not exclude the possibility of infection with a Candida species not detected due to errors in sample collection, transport, or storage.

**Methodology:** Genomic DNA was extracted and amplified by polymerase chain reaction (PCR) using primers specific for a conserved sequences common to the Candida genus. Concurrently, analysis of DNA integrity and the presence of inhibitory substances was evaluated by the amplification of the human Apolipoprotein B gene. PCR products were subjected to restriction endonuclease digestion and automated electrophoresis fluorescence detection. Digital electropherograms and gel images of data were generated and the specific Candida species was determined by matching the displayed banding pattern to known Candida species restriction fragment patterns. The analytical and performance characteristics of this laboratory-developed test (LDT) were determined by OralDNA Labs, A Service of Access Genetics, LLC pursuant to Clinical Laboratory Improvement Amendments (CLIA 88) requirements. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not a requirement prior to use for clinical purposes.

**References:**

- Al-Karaawi ZM, Manfredi M, Waugh AC, et al. Molecular characterization of Candida spp. isolated from the oral cavities of patients from diverse clinical settings. Oral Microbiol Immunol 2002;17:44-9.
- da Silva-Rocha WP, Lemos VL, Svidizinski TI, Milan EP, Chaves GM. Candida species distribution, genotyping and virulence factors of Candida albicans isolated from the oral cavity of kidney transplant recipients of two geographic regions of Brazil. BMC Oral Health 2014;14:20.



Ronald McGlennen MD, FCAP, FACMG, ABMG  
**Medical Director**

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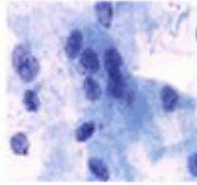
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**Reason for Testing:** Evaluation of suspicious lesion  
**Related info:** Not Provided  
**Patient History:** Not Provided

**Lesion Size:** 1mm x 1mm  
**Lesion Color:** White  
**Lesion Location(s):** Buccal Mucosa

**MOLECULAR IDENTIFICATION OF CANDIDA SPECIES IN THE OROPHARYNX**

Test Results	
Candida Species	C.albicans

<p><b>Signs &amp; Symptoms of Oral Candidiasis</b></p> <ul style="list-style-type: none"> <li>• Often no symptoms</li> <li>• "Burning mouth syndrome"</li> <li>• Metallic or acidic or salty taste</li> </ul>	 <p>Candida species</p>	<p><b>Causes</b></p> <ul style="list-style-type: none"> <li>• Various Candida species, most often C. albicans</li> <li>• Underlying systemic disease</li> <li>• Immunosuppression</li> </ul>
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**Interpretation:**

This sample is positive for Candida albicans DNA. This assay cannot rule out infection by Candida dubliniensis. See comments.

**Comments:**

- **Significance:** These findings support a diagnosis of oral candidiasis (Oral thrush) caused by C. albicans, the most commonly implicated organism in this condition. C. albicans may be present in normal flora. Oral thrush causes creamy white lesions, usually on the tongue or inner cheeks and may spread to the roof of mouth, gums, tonsils, or the back of the throat. Severe symptoms can make eating painful and difficult. Left untreated, thrush can spread to the digestive tract and intestines making it difficult to receive adequate nutrition. In immunocompromised individuals, thrush is more likely to spread to the lungs, liver and heart valves. It is not a type of infection that can be passed on to others.

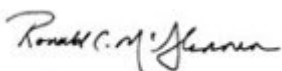
- **Risk:** Oral thrush most commonly affects people who wear dentures. People who have difficulties keeping their mouth clean, people with diabetes and those who take steroids are also at a higher risk of developing the condition. Some antibiotics may cause thrush. Certain antibiotics encourage the infection to recur, especially if taken over a long period of time. Very rarely, oral thrush may be one of the early signs of HIV.

- **Consider:** C. albicans accounts for about 50% of oral candidiasis cases, and together, C. albicans, C. tropicalis and C. glabrata account for over 80% of cases. Thrush should be treated to keep the infection from spreading. Prescribed antifungal medicines are the standard treatment for thrush either applied directly to the affected area (topical) or swallowed (oral). Severe infections may require a treatment period longer than 14 days. It is estimated that 1.5-2% of isolates identified as C. albicans are actually C. dubliniensis. C. albicans and C. dubliniensis are closely related Candida species therefore, may respond similarly to first-line treatment.

**Methodology:** Genomic DNA was extracted and amplified by polymerase chain reaction (PCR) using primers specific for a conserved sequences common to the Candida genus. Concurrently, analysis of DNA integrity and the presence of inhibitory substances was evaluated by the amplification of the human Apolipoprotein B gene. PCR products were subjected to restriction endonuclease digestion and automated electrophoresis fluorescence detection. Digital electropherograms and gel images of data were generated and the specific Candida species was determined by matching the displayed banding pattern to known Candida species restriction fragment patterns. The analytical and performance characteristics of this laboratory-developed test (LDT) were determined by OraIDNA Labs, A Service of Access Genetics, LLC pursuant to Clinical Laboratory Improvement Amendments (CLIA 88) requirements. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not a requirement prior to use for clinical purposes.

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