

P2197 Evaluation of the DermaGenius Nail Real-Time PCR Assay 2.0

Michelle Della Watson*¹, Jonathan Swindells¹, Ashok Dadrah¹

¹ Hospital, Birmingham, United Kingdom

Background: The DermaGenius® (DG) nail Assay 2.0 (PathoNostics, The Netherlands) is a real-time PCR assay which detects *Trichophyton rubrum*, *Trichophyton interdigitale* and *Candida albicans* from nail samples. The assay was evaluated at City Hospital, Birmingham.

Materials/methods: A retrospective study was performed using 14 nail samples which were previously culture positive. A verification test panel (PathoNostics) was used to ensure detection of all targets.

Nail samples (N=106) received between 10/07/2018 and 1/10/2018, were tested prospectively using microscopy, culture and PCR.

Samples were prepared for microscopy using 20% potassium hydroxide and lactophenol cotton blue and cultured using Glucose peptone agar plate supplemented with chloramphenicol and Cycloheximide and Glucose peptone agar plate supplemented with chloramphenicol.

The DG assay was performed according to manufacturer's instructions. The DNA extracts were analysed using the Rotor-Gene® (QIAGEN®) real-time PCR cycler. Results were determined by the cycle threshold (Ct) and melting curve analysis.

Results: For the retrospective testing, the sensitivity and specificity of the PCR assay was 100%. One sample was incorrectly identified by culture. All targets were detected using the verification panel.

Results of the prospective testing are summarised in the table below. Four culture negative samples where the internal control was inhibited and 3 samples which cultured pathogens not included in the detection panel have been excluded from the table.

	Culture positive	Culture negative	Total		
	Microscopy positive	Microscopy negative	Microscopy positive	Microscopy negative	
PCR positive	25*	4	23	6 [^]	58
PCR negative	2	0	5	34	41
Total	27	4	28	40	99

*1 sample incorrectly identified as *T. violaceum* by culture

[^] Samples undergoing further sequence based testing to resolve discrepancies

Sensitivity and specificity were calculated where there had been concordance in the other 2 tests. Based on current

results, the sensitivity of PCR is 92.6% with 85% specificity. The sensitivity of culture is 52% with 100% specificity. The sensitivity of microscopy is 86% with 87% specificity.

Conclusions: The DermaGenius® nail real-time PCR assay sensitivity was improved compared to culture and microscopy methods.

The PCR assay is a useful test and only PCR negative samples need microscopy. Culture is only needed if the microscopy positive.

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