

Fifteen-Minute Detection of *Streptococcus pyogenes* in Throat Swabs by Use of a Commercially Available Point-of-Care PCR Assay

James R. Uhl,^a Robin Patel^{a,b}

Division of Clinical Microbiology, Department of Laboratory Medicine and Pathology, Mayo Clinic, Rochester, Minnesota, USA^a; Division of Infectious Diseases, Department of Medicine, Mayo Clinic, Rochester, Minnesota, USA^b

Since 2002, our clinical microbiology laboratory has routinely performed *Streptococcus pyogenes* PCR on throat swabs using a previously described LightCycler assay which uses Roche analyte-specific reagent (ASR) primers and fluorescence resonance energy transfer (FRET) probes (1). The complexity of the assay required performance in the laboratory. Recently, the United States Food and Drug Administration (FDA) cleared a Clinical Laboratory Improvement Amendments (CLIA)-waived (exempt from CLIA requirements) rapid PCR assay for detection of *S. pyogenes* in throat swabs, the cobas Strep A test on the Liat system (Roche Diagnostics, Indianapolis, IN), a small, automated, closed PCR instrument that processes one specimen at a time in approximately 15 min. An internal process control (IPC) monitors sample preparation and real-time PCR. Negative results do not need culture backup. An Eswab (Copan Diagnostics, Inc., Murrieta, CA) is recommended to collect the throat swab. A few drops of specimen are added to the Strep A assay tube. The single-use assay tube provides all the components needed for sample extraction and amplification; the tube is placed into the Liat instrument and results are displayed after testing is complete.

We compared the cobas Liat strep A assay with our routinely used *S. pyogenes* LightCycler PCR assay (1). Two hundred throat swabs collected using CultureSwabs (Becton Dickinson Microbiology Systems, Cockeysville, MD) and submitted to our laboratory for *S. pyogenes* PCR were studied. The swabs were initially tested using the *S. pyogenes* LightCycler assay, as part of our routine clinical practice. Then, the Stuart's medium in the pledget, stored at 4°C, was squeezed into a collection tube. A 100- μ l portion of Stuart's medium was added to an Eswab transport container with 1 ml of Amies medium for the cobas Liat group A strep test. A second 100- μ l portion of Stuart's medium was used for a second LightCycler PCR assay, the results of which were analyzed here.

Eighty-four specimens produced positive results and 114 specimens were negative by both assays. Two specimens were only positive with the Liat assay. The sensitivity and specificity of the cobas Liat group A strep test were 100.0 and 98.3%, respectively, considering the LightCycler PCR assay as the gold standard. The positive and negative predictive values were 97.7% and 100.0%, respectively. The two specimens which were Liat strep A positive and negative with the second LightCycler PCR assay had been weakly positive by the first LightCycler PCR assay. No specimen

provided an invalid result with either test. A limitation of this study is that specimens were not collected using Eswabs.

We have demonstrated that the 15-min CLIA-waived PCR assay for *S. pyogenes* detection has performance equivalent to that of the LightCycler assay routinely used in our laboratory. The Liat strep A test is easy to use and requires virtually no training. The instrument provides an advance in PCR technology that may be advantageous to point-of-care sites, including physician offices, urgent-care locations, and hospital laboratories.

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REFERENCE

1. Uhl JR, Adamson SC, Vetter EA, Schleck CD, Harmsen WS, Iverson LK, Santrach PJ, Henry NK, Cockerill FR. 2003. Comparison of LightCycler PCR, rapid antigen immunoassay, and culture for detection of group A streptococci from throat swabs. *J Clin Microbiol* 41:242–249. <http://dx.doi.org/10.1128/JCM.41.1.242-249.2003>.

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Address correspondence to Robin Patel, patel.robin@mayo.edu.

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