

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2052935	(X3) Date Survey Completed 09/24/2021
Name of Provider or Supplier Medexpress Urgent Care - Culpeper	Street Address, City, State 1420 South Main Street, Culpeper, VA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An unannounced Clinical Laboratory Improvement Amendments (CLIA) complaint investigation (#VA00053133) was conducted at MedExpress Urgent Care-Culpeper on September 22, 2021 by a Medical Facilities Inspector from the Virginia Department of Health, Office of Licensure and Certification. The investigation included virtual interviews with the company Director of Quality & Patient Safety on 9/23/21 and 9/24/21. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. Based on a tour, review of documents and interviews, the inspector found one of the two complainant allegations to be substantiated. Specific deficiency related to the pre-analytic allegation is cited as follows:
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Food and Drug Administration (FDA) Emergency Use Authorization (EUA) Instructions for Use (IFU), manufacturer's package insert, laboratory policies, testing personnel (TP) competency assessments, lack of documentation, and interviews, the laboratory failed to provide documentation of required training for dual nares sample collection for the BD Veritor System Rapid Detection of SARS-CoV-S during the timeframe of December 2020 to the date of the investigation on 9/22/21. Findings include: 1. Review of the FDA's BD Veritor System for Rapid Detection of SARS-CoV-2 issued EUA (dated 03/31/21) revealed a manufacturer's IFU with the following statement: "Conditions of Authorization for Laboratory and Patient Care Setting: All operators using your product must be trained in performing and interpreting the results of your product, use appropriate personal</p>

protective equipment when handling this kit, and use the product in accordance with the authorized labeling." 2. Review of the BD Veritor System package insert revealed Specimen Collection and Handling instructions that stated: "Acceptable specimens for testing with this kit include nasal swab specimens obtained by the dual nares collection method. It is essential that correct specimen collection be followed. Inadequate specimen collection, improper specimen handling and/or transport may yield a falsely negative result; therefore, training in specimen collection is highly recommended due to the importance of specimen quality for generating accurate test results. Insert the swab into one nostril of the patient. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucous and cells are collected. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities." 3. Review of laboratory's policy MedExpress-Culpeper BD Veritor Sample Collection revealed a nasal swab protocol statement: "Carefully insert swab into the nostril less than an inch until it reaches the portion of the mucosa that is inflamed or contains exudate. Rotate the swab quickly." The inspector noted that the provided protocol lacked instructions to swab for dual nares collection. 4. During a follow up virtual interview with the company's Director Quality & Patient Safety and Training Systems Administrator (on 9/23/21 at approximately 8 AM, 9/24/21 at approximately 11 AM) the inspector inquired regarding access to BD Veritor's Rapid SARS-CoV-2 competency assessments and if the training included direct observations. The directors provided virtual documentation of the training/competency records that include checked observed collection verification statements: "Carefully insert swab into the nostril less than an inch until it reaches the portion of the mucosa that is inflamed or contains exudate. Rotate the swab quickly." The inspector noted that the provided training and competency records did not specify/outline collection from both of the patient nostrils (swabbing 5 times each) per the manufacturer's guideline. 5. An interview with the center director, on 9/24/21 at approximately 3:00 PM, the above findings were confirmed.