

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2033989	(X3) Date Survey Completed 09/10/2021
Name of Provider or Supplier Pathology Services For Jefferson Regional Mc	Street Address, City, State 1600 West 40th Avenue, Pine Bluff, AR	
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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Through a review of the laboratory policy and procedure manual, a review of the Histology Temperature Charts for 2020 and 2021, and interviews with laboratory staff, it was determined the laboratory failed to define an acceptable water bath temperature for the Flotation Water Bath. Survey findings follow: A. The Flotation Bath policy states, "Begin cutting temperature should be 40 to 43 degrees Celsius." B. The "Histology Temperature Chart" includes an acceptable water bath temperature of 36 to 40 degrees Celsius. C. Due to inconsistencies between the acceptable Flotation Bath temperature in the written policy and the acceptable temperature range on the "Histology Temperature Chart" there was no established acceptable temperature for the Flotation Water Bath. D. In an interview at 10:38 on 9/13/2021, laboratory employee #4 (as listed on the form CMS-209) confirmed the inconsistencies in acceptable temperatures for the water bath.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an</p>

ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Through a review of the GYN Cytology Quality Assurance Summaries for 2021 and interviews with laboratory staff, it was determined the laboratory failed to document corrective actions to correct problems identified in the 10% rescreen of GYN Cytology slides. Survey findings include: A. In a review of GYN Cytology Quality Assurance Summary for 1/1/2021 through 1/31/2021 revealed one patient (G-21-00169) with a discrepancy between the cytotech screen and the pathologist rescreen listed as a major upgrade. A review of GYN Cytology Quality Assurance Summary for 1/1/2021 through 2/28/2021 revealed one patient (G-21-00267) with a discrepancy between the cytotech screen and the pathologist rescreen listed as a major upgrade. B. The surveyor requested documentation of actions to address the discrepancies on the Quality Assurance Summaries for January and February 2021 but none was provided. C. In an interview, at 2:15 p.m. on 9/9/2021, employee #7 stated that the pathologist reviews the discrepancies "in real time" with the cytotech who originally screened the slides but there is no documentation.