

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2066598	(X3) Date Survey Completed 07/18/2019
Name of Provider or Supplier Sparrow Healthcare	Street Address, City, State 2408 Timberloch, Suite B-1, The Woodlands, TX	
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
D3045	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(b)</p> <p>If the laboratory ceases operation, the laboratory must make provisions to ensure that all records and, as applicable, slides, blocks, and tissue are retained and available for the time frames specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on review and laboratory records and interview with testing personnel (TP) #1 and #2, the laboratory failed to make provisions to ensure that all records are maintained and available for 2 years after the laboratory ceased operations on February of 2019. Findings Include: 1. On the day of survey, 07/18/2019, TP#1 and #2 revealed that the laboratory ceased patient testing February 2019 and resumed testing June 26th, 2019. 2. The laboratory was unable to provide the following documents from 07/18/2017 (last inspection date) to February 2019 (when lab stopped patient testing). - Laboratory test requisitions and test authorizations, including the patient's chart or medical records. - Laboratory quality control and patient test records. - Laboratory proficiency testing records. - Laboratory quality system assessment documents. - Original reports (including final, preliminary, and corrected reports) after the date of reporting. 3. TP #1 and #2 confirmed the findings above on 06/18 /2019 around 9:00 am.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p>

This STANDARD is not met as evidenced by:

Based on review of laboratory procedure manuals and interview testing personnel (TP) #1 and #2, the laboratory failed to establish a competency assessment procedure to assess the competency of consultants, supervisors and TP who performed hematology testing from 09/19/2017 to the date of survey. Findings Include: 1. On the day of survey, 07/18/2019, the laboratory could not provide a written procedure to assess the competency of consultants, supervisors and TP who performed complete blood count tests on the Abbott Diagnostics CELL-DYN Emerald analyzer from 09/19/2017 to 07/18/2019. 2. The laboratory could not provide the annual competency assessment for 1 of 2 TP (TP #1). 3. The TP #1 and #2 confirmed the findings above on 07/18/2019 around 09:40 am.