

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 34D1016970	<b>(X3) Date Survey Completed</b> 09/09/2019
<b>Name of Provider or Supplier</b> Hallmark Womens Clinic	<b>Street Address, City, State</b> 1919 Gillespie Street, Fayetteville, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2018 and 2019 American Proficiency Institute (API) proficiency testing (PT) records and interview with testing personnel (TP) and laboratory director (LD) 9/09/19, the laboratory failed to ensure that all attestation statements were signed by testing personnel and the laboratory director. Findings: Review of 2018 API PT Immunology/Immunoematology 2nd event revealed the laboratory director failed to sign the attestation statement. Review of 2019 APT PT Immunology /Immunoematology 1st event revealed TP #1 failed to sign the attestation statement. Exit interview with LD and TP #1 at approximately 11:00 a.m. confirmed the attestation statements for were not signed as required.</p>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with laboratory director (LD) and testing personnel (TP) 9/9/19, the laboratory failed to retain manufacturer's quality control assay sheets for the Rhesus antibody (RH) testing performed. Findings:</p>

The laboratory performs RH quality control testing using Quotient ALBAcyte reagent red blood cells. Review of laboratory records revealed the laboratory failed to retain manufacturer's assay sheets for the Quotient ALBAcyte reagent from time of last survey 9/6/17 until time of current survey, 9/9/19, a period of approximately 24 months in which manufacturer assay sheets were not retained. Exit interview with LD and TP #1 at approximately 11:00 a.m. confirmed the laboratory failed to retain the Quotient ALBAcyte reagent assay sheets. TP #1 stated she remembered they had saved them previously, but she had not retained them for the last 2 years. The LD stated that he thought they were to retain the receipt of purchase for the reagent, and did not realize they needed the manufacturer assay sheets.

**D5209**

**PERSONNEL COMPETENCY ASSESSMENT POLICIES**  
CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:

Based on review of laboratory procedure manual, review of laboratory records and interview with laboratory director 9/9/19, the laboratory failed to establish competency procedures that meet the regulations as stated in section 493.1413 (b) (8) of the 42 CFR Part 493 Requirements for Laboratories. Section 493.1413(b)(8) states: "The procedures for evaluation of the competency of the staff (testing personnel) must include, but are not limited to... Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; Monitoring the recording and reporting of test results; Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; Direct observation of performance of instrument maintenance and function checks; Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and Assessment of problem solving skills; Findings: Review of laboratory records and personnel records revealed a "Lab Test", used to document the evaluation of testing personnel (TP) competency. The "Lab Test" is a list of 6 questions that TP are to answer each year. The "Lab Test" fails to document the monitoring of the recording and reporting of test results, fails to document direct observation of patient test performance, fails to demonstrate a review of test results, worksheets, and quality control records, and fails to demonstrate an assessment of problem solving skills. Assessment of test performance is demonstrated by the laboratory for external proficiency testing by TP participation. Exit interview with LD at approximately 11:00 a.m. confirmed the "Lab Test" was used to document the evaluation of TP competency.

**D6091**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:

Based on review of 2018 and 2019 American Proficiency Institute (API) proficiency testing (PT) records and interview with laboratory director (LD) 9/09/19, the laboratory director failed to review all proficiency testing reports. Findings: Review of 2018 API PT Immunology/Immunohematology 2nd event revealed no documentation of the performance evaluation for the PT event and no documentation that the laboratory director reviewed the results of the PT event. Exit interview with LD at approximately 11:00 a.m. confirmed there was no documentation of the performance evaluation and no documentation of his review of the PT results. He stated the laboratory must have forgot to put it in the notebook, but was sure that he had reviewed it.