

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0961491	<b>(X3) Date Survey Completed</b> 11/15/2019
<b>Name of Provider or Supplier</b> Chickahominy Family Practice- Central Lab	<b>Street Address, City, State</b> 9010 Pocahontas Trail, Providence Forge, VA	
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>D0000</b>	An announced CLIA recertification survey was conducted at Chickahominy Family Practice-Central Lab on November 15, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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> <p>This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), procedure and policy manual, personnel files, and interviews, the laboratory did not establish/follow a policy for one (1) technical consultant's (TC) competency assessment in calendar year 2018 and up to the date of the survey on November 15, 2019. Findings include: 1. Review of the CMS 209 revealed that Personnel A serves as TC. (See Personnel Code Sheet.) 2. Review of the laboratory procedure and policy manual revealed no protocol outlining documentation of the competency assessment of the TC. 3. Review of the personnel files revealed that the laboratory director (LD) failed to document competency assessments in calendar year 2018 and year to date 2019 for Personnel A in the role of TC. 4. In an interview with the lead tech and LD, at approximately 2:30 PM, the above findings were confirmed.</p>
<b>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of</p>

the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), policies and procedures, manufacturer's package inserts, tour with review of temperature logs, and interviews, the laboratory failed to establish a policy that followed the manufacturer's instructions for storage of patient samples when testing was delayed, beyond the date of collection, for nine (9) chemistry analytes in the twenty-three (23) months reviewed. Findings include: 1. Review of the CMS 209 form revealed that one (1) testing personnel was identified as responsible for non-waived chemistry patient testing during the review timeframe of December 2017 to 11/15/19. The lead tech stated, at approximately 12:30 PM, "I am the only employee that runs the chemistry analyzers. On Friday afternoons, I leave at 2 PM and the nursing staff place patient samples in their refrigerator or freezer. I pick them up to run them on the following Monday. If I am off on vacation, the samples are handled in the same manner until I return". 2. Review of the laboratory's policy and procedure manual revealed a policy (titled "Stability for Siemens") that stated: "All samples are good refrigerated for 5-7 days with exception for albumin, calcium, cholesterol, CO<sub>2</sub>, and triglycerides which are good for 2 days refrigerated. Glucose is good for three days refrigerated and PSA is good for 8 hours and then must be frozen". The inspector noted that the policy failed to outline specific storage temperatures (refrigeration/freezer) when assays are delayed. 3. Review of the Siemens Dimension package inserts for Albumin (Alb), Calcium (Ca), Cholesterol (Chol), Carbon Dioxide (CO<sub>2</sub>), and Triglycerides (TGL) outlined in the policy above revealed manufacturer's specimen storage and stability requirements that stated: "Specimens are stable for 8 hours at room temperature; 2 days at 2-8 degrees C, for longer storage may be frozen at -20 C or colder". The inspector noted that the Siemens Glucose (GLU) package stated "sample is stable for as long as 8 hours at room temperature and up to 72 hours at 4 degrees C" and the Prostate Specific Antigen (PSA) package stated, "sample should be kept at 4 C and analyzed within 8 hours or frozen at -20 C or colder". Additionally, the following package insert instructions revealed specific time sensitive storage instructions: Total Protein (TP) - "specimens are stable for 8 hours at room temperature, 72 hours at 2-8 C, and stored 6 months if frozen at -20 C or cooler"; Uric Acid (URCA)- "specimens are stable 3-5 days at 2-8 C, and stored for up to 6 months if frozen at -20 C or cooler"; 4. During a tour of the nursing station in the facility, at approximately 1:30 PM, the inspector noted the facility utilized commercial (for home use) refrigerator freezers. Review of the nursing station laboratory temperature logs for: Frigidaire Model FRT173FW, Whirlpool 1583AW7, and Whirlpool W4TXNWFQ01 revealed that the freezer storage temperatures were not recorded for each day during 23 of the 23 months reviewed. The inspector reviewed the contents of Frigidaire Model FRT173FW and noted a thermometer reading of -10 C. The inspector stated the manufacturer's specimen storage requirements listed above to the lead tech and nurse. The lead tech and nurse, stated at approximately 2:00 PM, "our freezers in the nursing stations probably do not get as cold as -20 C". 5. In an interview with the lead tech and laboratory director, at approximately 2:30 PM, the above findings were confirmed.