

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0702896	<b>(X3) Date Survey Completed</b> 07/12/2022
<b>Name of Provider or Supplier</b> Hematology Oncology Assoc Of Fredericksburg	<b>Street Address, City, State</b> 4501 Empire Court, Fredericksburg, 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 Hematology Oncology Associates of Fredericksburg on July 12, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
<b>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> 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 laboratory tour, review of package insert, and interviews, the laboratory failed to follow the manufacturer's instructions for one (1) of 1 expired Influenza A &amp; B test kit stored in the laboratory on the date of the inspection, July 12, 2022. Findings include: 1. During a laboratory tour on 7/12/22 at approximately 10 AM, the inspector noted one (1) expired box of McKesson Consult Influenza A &amp; B kit (Lot Number 449K41, Expiration 10/31/2021). No other lot numbers of the expired Influenza A &amp; B test cassettes were stored in the laboratory. The inspector noted twenty-two (22) of twenty-five (25) test cassettes in the kit. 2. Review of the Influenza A &amp; B package insert revealed manufacturers instructions: "Do not use test cassettes beyond the kit expiration date. Discard after expiration." The inspector inquired regarding the expired test kit. The Technical Supervisor (TS) stated at approximately 12 noon, "The staff should have noted that the kit is not in use on the box". 3. An exit interview with the Lab Director, Exam/Lab Manager, and TS on 7/12/22 at approximately 3:30 PM confirmed the above findings.</p>

**D5215**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on a review of proficiency testing (PT) records and interviews, the laboratory failed to evaluate non-graded hematology and chemistry module PT results for two (2) of six (6) events reviewed for both Blood Cell Identification (BCI) and Cancer Antigen (CA) 19-9. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT notebooks, a total of 6 hematology and 6 core chemistry module events (2020 Event 3, 2021 Events 1-3, 2022 Events 1-2), revealed no documentation of an evaluation or verification of accuracy for the following non-graded responses: API Heme Module: 2020 Event 3- challenge sample BCI-11, one (1) of five (5) responses scored as "not graded"; 2021 Event 2- challenge sample BCI-07, 1 of 5 responses scored as "not graded"; API Core Chemistry Module: 2020 Event 3 - CA 19-9 challenges TM-11, TM-12, 2 of 2 responses scored as "not graded"; 2021 Event 1 - CA 19-9 challenges TM-01, TM-02, 2 of 2 responses scored as "not graded"; The PT notebooks' review pages recorded signatures of review by the lab director (LD) and Technical Supervisor (TS) with written comment "100%" for the above outlined events. 2. An exit interview with the LD, Exam/Lab Manager, and TS on 7/12/22 at approximately 3:30 PM confirmed the above findings.