

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2107872	(X3) Date Survey Completed 06/28/2021
Name of Provider or Supplier Shands Jacksonville Medical Ctr DbA	Street Address, City, State 2141 Loch Rane Blvd Ste 116, Orange Park, FL	
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
D0000	An announced CLIA recertification survey was conducted at UF Health Oncology Orange Park on 6/28/2021. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. .
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to test proficiency samples the same number of times that it routinely tests patient samples for the 1st and 2nd Hematology/Coagulation testing events in 2020 and the 1st Hematology/ Coagulation testing event of 2021. Findings include: Record review revealed American Proficiency Institute samples were run twice for tests: Red Cell Count, Hemoglobin, Hematocrit, Platelet Count, White Cell Count, Mean Corpuscular Volume, Mean Corpuscular Hemoglobin, Mean Corpuscular Hemoglobin Concentration, Red Cell Distribution Width, Neutrophil, Lymphocyte, Monocyte, Eosinophil, and Basophil. For the 1st testing event of 2020, samples were run on 3/17/2020 as follows: XE-01 was run at 07:28 and 07:36 XE-02 was run at 07:29 and 07:37 XE-03 was run at 07:30 and 07:38 XE-04 was run at 07:31 and 07:39 XE-05 was run at 07:32 and 07:40 For the 2nd testing event of 2020, samples were run on 7/10/2020 as follows: XE-06 was run at 14:31 and 14:39 XE-07 was run at 14:32 and 14:40 XE-08 was run at 14:33 and 14:41 XE-09 was run at 14:34 and 14:42 XE-10 was run at 14:36 and 14:43 For the 1st testing event of 2021, samples were run on 3/11/2021 as follows: XE-01 was run at 11:18 and 15:48 XE-02 was run at 11:20 and 15:49 XE-03 was run at 11:21 and 15:50 XE-04 was run at 11:22 and 15:51 XE-05 was run at 11:23 and 15:53 Interview with the Technical Consultant on 6/28/2021 at 12:15 confirmed testing personnel had run proficiency samples multiple times for the 1st Hematology/</p>

Coagulation testing event of 2021, and the 1st and 2nd Hematology/ Coagulation testing events in 2020. .

D2015

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on record review and interview, the facility failed to sign and date proficiency testing attestation forms for two out of five events reviewed (2019 - 2021). Findings include: Record review revealed the American Proficiency Institute, 2020 Hematology /Coagulation 1st and 2nd testing events, attestation forms were not signed and dated by testing personnel and the lab director. Interview with the Technical Consultant on 6 /28/2021 at 12:15 confirmed attestation forms were not signed and dated by testing personnel and the lab director.