

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2152424	<b>(X3) Date Survey Completed</b>  08/01/2022
<b>Name of Provider or Supplier</b>  Csi Laboratories	<b>Street Address, City, State</b>  2141 Alternate A1a #305, Jupiter, FL	
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 recertification survey was conducted on 7/27/22 through 8/1/22 at CSI Laboratories, a clinical laboratory in Jupiter, Florida. CSI Laboratories is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is a description of the noncompliance.
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify accuracy of the flow cytometry antibodies at least twice annually in 2021. The findings included: The laboratory used flow cytometry to detect and analyze the chemical and physical characteristics of cells in bone marrow, peripheral blood, tissue, and other body fluids. The laboratory used the following antibodies: CD10 (Cluster of Differentiation), CD103, CD117, CD11b, CD11c, CD123, CD13 CD13/CD33, CD138, CD14, CD16, CD19, CD2, CD20, CD200, CD22, CD23, CD25, CD3, CD30, CD33, CD34, CD38, CD4, CD45, CD49d, CD5, CD56, CD57, CD64, CD7, CD71, CD8, , HLA-DR (Human Leukocyte Antigen - DR isotype), Kappa, and Lambda. Review of the laboratories proficiency testing (PT) records showed a comparison was performed with the Georgia laboratory on a bone marrow sample from 01/20/2021. The bone marrow/peripheral blood panel consisting of 4 tubes and the multiple myeloma tube was evaluated. The following antibodies were not evaluated: CD103, CD200, CD25, CD30, and CD49d. No other PT for 2021 was available for review. On 07/27/2022 at 4:45PM, the Laboratory Manager stated a second PT in 2021 was sent to Georgia for comparison and the sample was rejected, and no other PT was performed in 2021.</p>
<b>D5805</b>	TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to include name and address of the laboratory where the technical component was performed for five of five patients' laboratory test reports, (#1, #2, #3, #4, #5). The findings included: Review of patients' Flow Cytometry Report showed the name and address of the laboratory where the technical component was performed was not listed on the reports.. According to the Clinical Laboratory Improvement Amendment (CLIA) Application for Certification, signed and dated by the Laboratory Director on 07/27/2022, the laboratory's annual test volume was 28,700 tests. On 07/27/2022 at 5:04 PM, Testing Personnel B confirmed the name and address of the laboratory where the technical component was performed was not on the Flow Cytometry Reports.