

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2176388	(X3) Date Survey Completed 12/15/2020
Name of Provider or Supplier Charles River Laboratories Cell Solutions, Inc	Street Address, City, State 672 Suffolk St, Lowell, MA	
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 initial CLIA certification survey was conducted for the Key Biologics, LLC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform complete validation studies for one (1) newly implemented test system prior to reporting out patient testing results as evidenced by the following: Day to day precision: A review of validation studies for the Pentra XL 80 hematology analyzer. revealed that the laboratory failed to include day to day precision studies as part of the validation for all six (6) of the complete blood count (CBC) measured test analytes being performed (white blood count, red blood count, hemoglobin, mean corpuscular volume, platelet count, and white cell differential) prior to utilizing the analyzer for patient testing and reporting. The technical consultant confirmed in a telephone interview on 12/15/20 at 10:20 AM that the day to day precision studies were had not been completed. The laboratory performs 7,200 CBCs annually. .</p>
D6049	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii)</p>

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on record review and interview, the technical consultant failed to evaluate competency of the staff through review of quality control records as evidenced by the following: 1. A review of hematology quality control records from May to November 2020 was performed. Documentation was not available to verify that the technical consultant regularly reviewed quality control data to ensure that personnel were following established quality control policies and procedures and to ensure the accuracy and reliability of patient test results. The only documented review by the technical consultant was for June of 2020. 2. The technical consultant confirmed in a telephone interview on 12/15/20 at 10:21 AM. that quality control results for hematology had not been reviewed by her.