

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2159614	(X3) Date Survey Completed 04/29/2021
Name of Provider or Supplier Cgt Global	Street Address, City, State 1230 Soldiers Field Rd, Suite 2, Boston, 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 StemExpress laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: . Based on surveyor review of Hematology test records, lack of proficiency testing records, and staff interview, the laboratory failed to enroll in an approved proficiency testing program for Hematology. Findings include: 1. Record review conducted on 04/29/21 of testing records revealed that the laboratory began Hematology testing March 2019. 2. Staff interview conducted on 04/29/21 at 11:00 AM with the Technical Consultant 2 confirmed that the laboratory started Hematology testing during March 2019 and did not enroll in an approved proficiency testing program for 2019, 2020, and 2021. 3. The laboratory's estimated Completed Blood Count (CBC) annual test volume is 1,000. .</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p>

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:

. Based on record review and interview on 4/29/21, the laboratory failed to retain quality control (QC) records for at least 2 years as evidenced by the following: 1. Surveyors reviewed Hematology QC records for calendar years 2019, 2020, and 2021 on 4/29/21. The review revealed that the laboratory did not retain QC result records since the laboratory started testing on 3/4/2019 until 4/16/21. 2. Technical Consultant 1 confirmed in an interview on 4/29/21 at 11:30 AM that the laboratory documented whether QC was run and within range but did not retain the QC results until 4/16/21. 3. The laboratory's estimated Completed Blood Count (CBC) annual test volume is 1,000.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

. Based on record review and interview on 4/29/21, the laboratory failed to follow policies and procedures in place for all tests, assays, and examinations performed by the laboratory as evidenced by the following: 1. The surveyors reviewed the pocH-100i Hematology Analyzer procedure manual on 4/29/21. Section 5.1 Quality Control (QC) Procedures states, "Remove all 3 vials of the control material from the refrigerator and equilibrate to room temperature (18 - 30 degrees C) for 15 minutes before mixing." 2. The surveyors requested to review room temperature records of the laboratory space where QC material is equilibrated. Technical Consultant (TC) 1 and TC 2 stated that room temperature is not checked or documented in the laboratory. 3. TC 1 and TC 2 confirmed in an interview on 4/29/21 at 1:30 PM that the laboratory failed to follow their procedure manual ensuring that QC material is equilibrated within acceptable room temperature requirements. .

D5407

PROCEDURE MANUAL

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

. Based on procedure manual review and interview on 4/29/21, the laboratory director (LD) failed to approve, sign, and date laboratory procedures as evidenced by the following: 1. Surveyors reviewed the laboratory's procedure manuals on 4/29/21. The review revealed that the LD did not approve, sign, and date all laboratory policies and

procedures before use. 2. The Operations Director confirmed in an interview on 4/29/21 at 1:00 PM that the LD did not approve, sign, and date all laboratory policies and procedures before use. .

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

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.

This STANDARD is not met as evidenced by:

. Based on lack of documentation and interview with the Technical Consultant (TCs), the laboratory failed to verify the performance specifications of the Sysmex Poch-100i Hematology Analyzer prior to reporting patient test results. Findings include: 1. Record review conducted on 04/29/21 of patient testing records revealed that the laboratory began Hematology testing using the Sysmex Poch-100i Hematology Analyzer on March 2019. 2. Record review conducted on 04/29/21 revealed no documentation indicating that the laboratory verified the performance of the performance specifications of the Sysmex Poch-100i Hematology Analyzer prior to reporting patient test results. 3. Staff interview with TC2 on 04/29/21 at 11:30 am confirmed that the laboratory did not verify the performance specifications of the Sysmex Poch-100i Hematology Analyzer prior to reporting patient test results.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

. This Condition is not met as evidenced by: Based on record review and staff interview, the Technical Consultants (TCs) failed to provide technical oversight in accordance with 493.1413. The TCs failed to verify the performance specifications of the Sysmex Poch-100i Hematology Analyzer prior to reporting patient test results (refer to D6040); failed to enroll in an approved proficiency testing (PT) program for 2019, 2020, and 2021 (refer to D6041); and failed to establish a quality control (QC) program appropriate for Hematology Complete Blood Counts (refer to D6042). .

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:
. Based on lack of documentation and interview with the Technical Consultants (TCs) on 4/29/21, the TCs failed to fulfill the responsibility for verification of the laboratory's test performance characteristics as evidenced by the following: 1. Surveyors requested to review validation records for the Sysmex Poch-100i Hematology Analyzer on 4/29/21. The review revealed no documentation indicating that the laboratory verified the performance specifications of the Hematology Analyzer prior to reporting patient test results starting on 3/4/19. 2. TC confirmed in an interview on 04/29/21 at 11:30AM that the TC did not verify the performance specifications of the Sysmex Poch-100i Hematology Analyzer prior to reporting patient test results. 3. Refer to D5421.

D6041

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(3)

(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

This STANDARD is not met as evidenced by:
. Based on lack of documentation and interview with the Technical Consultants (TCs) on 4/29/21, the TCs failed to enroll and participate in an HHS approved proficiency testing (PT) program commensurate with the services offered as evidenced by the following: 1. The laboratory began Hematology patient testing on 3/4/2019. 2. The surveyors requested to review Hematology PT documentation from calendar years 2019, 2020, and 2021 on 4/29/21. The review revealed that that lab did not enroll in PT. 3. TC 2 confirmed in an interview on 4/29/21 at 11:00 AM that the TCs failed to enroll in an approved PT program for 2019, 2020, and 2021. 4. The laboratory's estimated Completed Blood Count (CBC) annual test volume is 1,000. 5. Refer to D2000. .

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:
. Based on quality control (QC) record review and interview on 4/29/21, the Technical Consultants (TCs) failed to establish a QC program appropriate for Hematology testing as evidenced by the following: 1. Surveyors reviewed QC records from calendar years 2019, 2020, and 2021. The review revealed that the TCs did not retain QC result records from 3/4/19 to 4/16/21 and did not monitor QC results for shifts and trends. 2. TC 1 confirmed in an interview on 4/29/21 at 11:30 AM that the TCs did not establish a QC program appropriate for Hematology Complete Blood Counts.