

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2243490	<b>(X3) Date Survey Completed</b>  07/07/2023
<b>Name of Provider or Supplier</b>  Stemexpress	<b>Street Address, City, State</b>  325 W Germantown Pike, Suite 200, East Norriton, PA	
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>D3009</b>	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by:</p> <p>A. Based on the review of personnel records and interviews with the Technical Consultant (TC) (CMS 209 personnel #2) and Laboratory Operations Manager, the laboratory failed to ensure that the State of Pennsylvania (PA) regulations were met regarding having a supervisor who met the qualifications specified in the Pennsylvania (PA) Clinical Lab Act from 12/06/2022 to 07/07/2023. Findings include: 1. The PA regulations (5.23 (a)(2) and (3)) states: "No person shall be a supervisor in a clinical laboratory unless he conforms with the following requirements: (2) He shall hold a M.A. or M.S. degree from an accredited institution with a major in medical technology or one of the biological, physical or chemical sciences and shall have had at least 4 years' experience acceptable to the Department in one or more of the applicable categories in the clinical laboratory. (3) He shall hold a B.S. or A.B. degree from an accredited institution with a major in medical technology or one of the biological, physical or chemical sciences and shall have had at least 6 years' experience acceptable to the Department in one or more of the applicable categories in the clinical laboratory." 2. On the day of survey, 07/7/2023 at 09:56 am, review of personnel credentials revealed that 1 of 1 TC has a Master's in Science degree in Nursing Leadership/Legal Nurse Consultant (completed in 2022). 3. The laboratory provided additional information via email that 1 of 1 TC has a Bachelor of Science degree in Nursing (completed in 2011) and has three years of clinical laboratory experience in the designated area. 4. The laboratory was unable to provide the acceptable experience needed for 1 of 1 TC in order to perform the duties of a supervisor in the state of Pennsylvania. 5. The TC and Laboratory Operations</p>

Manager confirmed the findings above on 07/07/2023 around 12:30 pm. B. Based on surveyor record review and interviews with the Technical Consultant (TC) (CMS 209 personnel #2) and Laboratory Operations Manager, the laboratory failed to ensure that the State of Pennsylvania (PA) regulations were met for having a supervisor on site during all normal scheduled working hours in which tests are performed from 12/06/2022 to the date of survey. Findings include: 1. The PA regulations (5.23 (b)(1)) states: "A general supervisor who meets all the requirements of subsection (a)(1), (2) or (3) and is on the laboratory premises during all normal scheduled working hours in which tests are being performed." 2. The laboratory personnel #2 is listed as the only Technical Consultant (TC) on the Laboratory Personnel Report form. 3. The laboratory was unable to provide the acceptable experience needed for 1 of 1 TC in order to perform the duties of a supervisor in the state of Pennsylvania. 4. On the day of survey, 07/7/2023 at 09:56 am, during an interview, laboratory personnel #2 stated that the TC is the only supervisor who is onsite for every hour of patient testing.

**D3031**

**RETENTION REQUIREMENTS**  
CFR(s): 493.1105(a)(3)

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 review of laboratory quality control (QC) records and interviews with the Technical Consultant (TC) (CMS 209 personnel #2) and Laboratory Operations Manager, the laboratory failed to retain instrument printouts for Symex pocH-100i Hematology analyzer background check from 12/06/2022 to 06/27/2023. Findings include: 1. On the day of survey, 07/7/2023 at 11:15 am, the laboratory could not provide background check records for CBC examinations performed from 12/06/2022 to 06/27/2023. 2. The TC and Laboratory Operations Manager confirmed the findings above on 07/07/2023 around 12:30 pm.

**D5209**

**PERSONNEL COMPETENCY ASSESSMENT POLICIES**  
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory procedures, competency assessment records and interviews with the Technical Consultant (TC) (CMS 209 personnel #2) and Laboratory Operations Manager, the laboratory failed to establish written policies and procedures to assess the competency of 4 of 5 testing personnel (TP) performing hematology testing and 1 of 1 technical consultant (TC) for their supervisory responsibilities from 12/06/2022 to 07/07/2023. Findings include: 1. On the day of the survey, 07/7/2023 at 10:25 am, the laboratory could not provide a written procedure to assess the competency for 4 of 5 TP (CMS 209, personnel # 3, 4, 5 and 6) who perform hematology testing. 2. The laboratory could not provide competency

assessment records for 1 of 1 TC for their supervisory responsibilities in 2022 and 2023. 3. The TC and Laboratory Operations Manager confirmed the findings above on 07/07/2023 around 12:30 pm.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of the College of American Pathologists (CAP) proficiency testing (PT) records, lack of documentation, and interviews with the Technical Consultant (TC) (CMS 209 personnel #2) and Laboratory Operations Manager, the LD failed to ensure that 1 of 2 CAP PT reports were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective actions in 2023. Findings include: 1. On the day of survey, 07/7/2023 at 10:42 am, review of the CAP PT records for 2023 revealed the following: - Corrective action was not documented for the CAP PT report (2023 CAP Event # 1 Hematology Auto Differentials): Red Blood Cell Count (60%), Hematocrit (80%), Hemoglobin (80%). 2. The TC and Laboratory Operations Manager confirmed the findings above on 07/07 /2023 around 12:30 pm.