

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0966159	(X3) Date Survey Completed 03/05/2020
Name of Provider or Supplier Hshs St Elizabeth's Hospital Convenient Care	Street Address, City, State 1512 N Green Mount Rd, O Fallon, IL	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of laboratory records, and interview with the laboratory's technical consultant (TC); the laboratory failed to perform and document preventative maintenance for hematology testing on the Sysmex XS-1000i analyzer in 2019 through 2020. Findings Include: 1. During tour of the laboratory on 3-4-2020 at 10:20 am, the surveyor observed patients' specimens being tested on a Sysmex XS-1000i, serial number 73724. 2. Review of the manufacturer's instructions for use manual for the Sysmex XS-1000i outlined the preventative maintenance schedule on pages 9-2 through 9-4, which stated the following for daily and monthly maintenance: a. "9.2 Daily maintenance 1. Execution of Shutdown When shutdown is performed, the dector and dilution line are cleaned. Put the instrument through a shudown cycle at the end of each day's analyses or at least once every 24 hours if running the instrument continuously." b. "9.3 Monthly maintenance Carry out Monlthy maintenance every month, or after every 1,200 analyses." 3. Review of preventative maintenance documentation for the Sysmex XS-1000i revealed the laboratory failed to document the performance of daily and monthly preventative maintenance. 4. On survey date 3-05-2020, at 12:30 pm, the TC confirmed the laboratory the laboratory failed to document daily and weekly preventative maintenance of the Sysmex XS-1000i analyzer.</p>
D6032	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</p>

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with the laboratory's technical consultant (TC); the laboratory director failed to identify the responsibilities and duties of each person engaged in all phases of testing. Findings Include: 1. No duties and responsibilities were specified in writing for 11 of 11 testing personnel listed on the CMS-209. 2. No duties and responsibilities were specified in writing for the laboratory director, clinical consultant, and technical consultant. 3. On survey date 3-05-2020, at 3:00 pm, the TC confirmed the laboratory failed to specify in writing the duties and responsibilities for each person engaged in testing process.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with the laboratory's technical consultant (TC); the TC failed to ensure semi-annual competency assessments for chemistry/hematology testing on the Alere Triage meter and hematology testing on the Sysmex XS-1000i analyzers were completed for 9 of 9 testing personnel. Findings Include: 1. Review of the CMS-209 (Laboratory Personnel Report) identified 9 new testing personnel (TP), TP#1, 2, 4, 5, 6, 8, 9, 10, and 11. 2. Interview with the TC on 3-5-2020, at 12:30 pm, confirmed all testing personnel listed on the CMS-209 perform d-dimer and cardiac panel (troponin I, myoglobin, creatine kinase-MB) testing on the Alere Triage meter and complete blood counts on the Sysmex XS-1000i analyzer. 3. Review of competency assessment records for TP#1, 2, 4, 5, 6, 8, 9, 10, and 11 revealed the laboratory failed to document the semi-annual competency assessments as follows for each individual: a. TP#1 - No semi-annual competency assessments in 2018 for complete blood counts, d-dimer, and cardiac panel b. TP#2 - No semi-annual competency assessments in 2019 for complete blood counts, d-dimer, and cardiac panel. c. TP#4 - No semi-annual competency assessments in 2019 for complete blood counts, d-dimer, and cardiac panel. d. TP#5 - No semi-annual competency assessments in 2019 for complete blood counts, d-dimer, and cardiac panel. e. TP#6 - No semi-annual competency assessments in 2019 for complete blood counts, d-dimer, and cardiac panel. f. TP#8 - No semi-annual competency assessments in 2019 for complete blood counts, d-dimer, and cardiac panel. g. TP#9 - No semi-annual competency assessments in 2019 for complete blood counts, d-dimer, and cardiac panel. h. TP#10 - No semi-annual competency assessments in 2019 for complete

blood counts, d-dimer, and cardiac panel. i. TP#11 - No semi-annual competency assessments in 2019 for complete blood counts, d-dimer, and cardiac panel. 4. On survey date 03-05-2020, at 3:00 pm the surveyor's findings were confirmed by the TC.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with the laboratory's technical consultant (TC); the TC failed to ensure annual competency assessments for chemistry /hematology testing on the Alere Triage meter and hematology testing on the Sysmex analyzers were completed for 2 of 2 testing personnel in 2018 and 2019. Findings Include: 1. Review of the CMS-209 (Laboratory Personnel Report) identified 2 established testing personnel, TP#3 and TP#7. 2. Interview with the TC on 3-5-2020, at 12:30 pm, confirmed all testing personnel listed on the CMS-209 perform d-dimer and cardiac panel (troponin I, myoglobin, creatine kinase-MB) testing on the Alere Triage meter and complete blood counts on the Sysmex XS-1000i analyzer. 2. Review of competency assessment records for TP#3 and TP#7 revealed the laboratory failed to document annual competency assessment for each individual as follows: a. TP#3 - No 2018 annual competency assessment for complete blood counts. b. TP#7 - No 2018 and 2019 competency assessments for complete blood counts, d-dimer, and cardiac panel. 3. On survey date 03-05-2020, at 3:00 pm the surveyor's findings were confirmed by the TC.

D6055

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with the laboratory's technical consultant (TC); the TC failed to ensure 6 of 11 testing personnel (TP) were evaluated on the new Sysmex XS-1000i instrumentation prior to reporting patient test results. Findings Include: 1. Review of the CMS-209 (Laboratory Personnel Report) identified 11 personnel performing moderate complexity testing. 2. Interview with the TC on 3-5-2020, at 12:30 pm, confirmed all testing personnel listed on the CMS-209 perform complete blood counts on the Sysmex XS-1000i analyzer. 3. Interview with the TC on 03-05-2020, at 12:40pm, confirmed the laboratory started patient testing on July 1, 2019 with the new Sysmex XS-1000i analyzer. 3. Review of training documentation revealed the laboratory failed to document training on the new Sysmex XS-1000i analyzer for 6 of 11 TP (TP#4, #5, #8, #9, #10, #11), as identified on the CMS-209. 4. On survey date 03-05-2020, at 3:00 pm the surveyor's findings were confirmed by the TC.

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on review of laboratory records and interview with the technical consultant (TC); the laboratory failed to employ testing personnel (TP) who met the qualification requirements of 493.1423. Findings Include: 1. The laboratory failed to have appropriate training documentation for 4 of 6 testing personnel qualifying with a high school diploma or equivalent degree. See D6066.

D6066

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with the technical consultant (TC); the laboratory failed to have appropriate training documentation for 4 of 6 testing personnel qualifying with a high school diploma or equivalent degree. Findings Include: 1. Review of the CMS-209 (Laboratory Personnel Report), identified 9 new testing personnel (TP), TP#1, 2, 4, 5, 6, 8, 9, 10, and 11. 2. Review of educational records for the 9 new TP found 6 of the 9 were qualified with a high school diploma or equivalent degrees, TP#1, 2, 4, 5, 6, and 11. 3. Interview with the TC on 3-5-2020, at 12:30 pm, confirmed all testing personnel listed on the CMS-209 perform d-dimer and cardiac panel (troponin I, myoglobin, creatine kinase-MB) testing on the Triage meter and complete blood counts on the Sysmex XS-1000i. 4. Review of training documentation revealed the laboratory failed to ensure 4 of 6 TP received the required appropriate training for chemistry and/or hematology testing prior to patient testing. a. TP#1 - No documented training for D-Dimer and Cardiac Panel testing on the Triage meter. b. TP#2 - No documented training for D-Dimer and Cardiac Panel testing on the Triage meter. c. TP#5 - No documented training for D-Dimer and Cardiac Panel testing on the Triage meter and complete blood count esting on the Sysmex XS-1000i analyzer. d. TP#11 - No training for complete blood count testing on the Sysmex XS-1000i analyzer. 5. On survey date 3-05-2020, at 3:00 pm, the surveyor's findings were confirmed by the TC.