

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0868635	(X3) Date Survey Completed 06/25/2020
Name of Provider or Supplier Shriners Hospital For Children Philadelphia	Street Address, City, State 3551 N Broad Street, Philadelphia, PA	
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
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Siemens Rapid Point 500 analyzer records and interview with the laboratory director (LD) and technical consultant (TC), the laboratory failed to evaluate the relationship between 2 of 2 Siemens Rapid Point 500 blood gases analyzers in 2018, 2019 and 2020. Findings include: 1. On the day of survey, 06/25/2020, the laboratory could not provide comparison studies performed on 2 of 2 Siemens Rapid Point 500 analyzers used for blood gases analysis in 2018, 2019 and 2020. 2. From 08/24/2018 to 12/31/2018, 431 patient specimens were analyzed on the Siemens Rapid Point 500 blood gases analyzers. 3. From 01/01/2019 to 12/31/2019, 1196 patient specimens were analyzed on the Siemens Rapid Point 500 blood gases analyzers. 4. From 01/01/2020 to 06/25/2020, patient specimens were analyzed on the Siemens Rapid Point 500 blood gases analyzers. 5. The LD and TC confirmed the findings above on 06/25/2020 around 10:00 am.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <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</p>

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 American Proficiency Institute (API) proficiency testing (PT) records and interview with the laboratory director (LD) and technical consultant (TC), the LD failed to ensure that all proficiency testing reports received, identified problems that require corrective action in 2019 and 2020. Findings include: 1. On the day of survey, 06/25/2020, review of API PT records revealed the laboratory did not document corrective actions for the following API PT results: - 2019 - Chemistry Event #1- potassium - 80% - 2019 - Hematology Event #1- Hemoglobin - 80% - 2019 - Hematology Event #1- Hematocrit - 80% - 2020 - Hematology Event #1 - Carboxyhemoglobin - 80% - 2020 - Hematology Event #1 - Methemoglobin - 80% - 2020 - Hematology Event #1 - Oxyhemoglobin - 80% 2. The LD and TC confirmed the findings above on 06/25/2020 around 9:40 am

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of laboratory personnel competency assessment record and interview with the laboratory director (LD) and technical consultant (TC), the TC failed to evaluate provide competency assessments for 2 of 14 testing personnel in 2018. Findings include: 1. On the day of survey, 06/25/2020, the TC could not provided competency assessment documentation for 2 of 14 TP (TP#8 and TP#10), for blood gases testing performed on the Siemens Rapid Point 500 analyzers. 2. The LD and TC confirmed the findings above on 06/25/2020 around 11:15 am.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:
Based on review of competency assessment records and interview with laboratory director (LD) and technical consultant (TC) the technical consultant, failed to assess the competency of 14 of 14 testing personnel (TP) through internal blind testing samples or external (PT) samples in 2018, 2019 and 2020. Findings include: 1. On the day of survey, 06/25/2020, review of 14 of 14 TP competency assessment records revealed, the annual competency assessment did not include the assessment through internal blind testing samples or external (PT) samples in 2018, 2019 and 2020. 2. The LD and TC confirmed the findings above on 06/25/2020 around 9:45 am.