

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0670561	(X3) Date Survey Completed 07/17/2019
Name of Provider or Supplier Children's Home Of Pittsburgh, The	Street Address, City, State 5324 Penn Avenue, Pittsburgh, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure manuals and interview with the administrative director of lab services, quality and compliance manager, nursing manager, clinical nurse educator, laboratory director (LD) and technical consultant (TC), the laboratory failed to establish a complete competency assessment procedure to assess the competency of 1 of 1 consultant and 5 of 79 TP who performed chemistry and hematology testing from 12/11/2017 to the date of survey. Findings Include: 1. On the day of survey, 07/17/2019, the laboratory could not provide a written procedure to assess the competency of 1 of 1 consultants from 12/11/2019 to 07/17/2019. 2. The laboratory could not provide the annual competency assessment for 1 of 1 TC (Personnel #3 on the CMS 209 form, Laboratory Personnel Report). 3. The laboratory could not provide annual competency assessments for the following personnel not listed on the CMS 209 form for signing off on testing personnel competencies annually: - TP #24 on page 3 of 6 - TP #41 on page 4 of 6 - TP #62 on page 5 of 6 - TP #66 on page 6 of 6 - TP #68 on page 6 of 6 4. The administrative director of lab services, quality and compliance manager, nursing manager, clinical nurse educator, LD and TC confirmed the findings above on 07/17/2019 around 09:15 am.</p>
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations</p>

Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of quality control records and interview administrative director of lab services, quality and compliance manager, nursing manager, clinical nurse educator, laboratory director (LD) and technical consultant (TC), the laboratory failed to perform external liquid quality controls (QC) of different concentration, each day of patient testing for blood gases and Hemoglobin tests performed on the Abbott I-Stat, EG7+ and EC8+ cartridges from 2018 to the day of survey. Findings include: 1. On the days of survey, 07/17/2019, review of I-Stat quality control records revealed, the laboratory performed external quality control for the Abbott I-Stat analyzer, and EC8+ cartridges on a weekly bases. 2. In 2018, 946 I-stat, EG7+ cartridge tests were performed. 3. In 2018, 178 I-stat, EC8+ cartridge tests were performed. 4. In 2019 (01/01/2019 to 07/17/2019), 503 I-stat, EG7+ cartridge tests were performed. 5. In 2019 (01/01/2019 to 07/17/2019), 49 I-stat, EC8+ cartridge tests were performed. 6. The administrative director of lab services, quality and compliance manager, nursing manager, clinical nurse educator, LD and TC confirmed the findings above on 07/17/2019 around 9:55 am.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(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.

This STANDARD is not met as evidenced by:

Based on review of Abbott I-Stat analyzer, EG7+ and EC8+ cartridge comparison records and interview with the administrative director of lab services, quality and compliance manager, nursing manager, clinical nurse educator, laboratory director (LD) and technical consultant (TC), the laboratory failed to evaluate the relationship between the 1 of 3 Abbott I-stat analyzer at least twice annually in 2018. Findings Include: 1. On the day of survey, 07/17/2019, review of the Abbott I-Stat analyzer, EG7+ and EC8+ cartridges comparison logs revealed, the laboratory did not perform comparisons on 2 of 3 I- stat's in use at least twice annually. - On 7/13/2018, comparison studies were performed on the pink and green I-stat's for the EG7+ and EC8+ cartridges, but not for the red I-stat. - On 3/18/2018, comparison studies were performed on the red and green I-stat's for the EG7+ and EC8+ cartridges, but not for the pink I-stat. 2. The 2018 comparisons were performed on the green I-stat twice a year, while the pink and red I-stat's were performed only once. 3. In 2018, 946 I-stat, EG7+ cartridge tests were performed. 4. In 2018, 178 I-stat, EC8+ cartridge tests were performed. 5. In 2019 (01/01/2019 to 07/17/2019), 503 I-stat, EG7+ cartridge tests were performed. 6. In 2019 (01/01/2019 to 07/17/2019), 49 I-stat, EC8+ cartridge tests were performed. 7. The administrative director of lab services, quality and compliance manager, nursing manager, clinical nurse educator and TC confirmed the findings above on 07/17/2019 around 10:45 am.

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 College of American Pathologists (CAP) proficiency testing (PT) records, and interview with the administrative director of lab services, quality and compliance manager, nursing manager, clinical nurse educator, laboratory director (LD) and technical consultant (TC), the laboratory failed to ensure 1 of 3 PT events (event #2) received in 2018 identified problems that required corrective action. Findings include: 1. On the day of survey, 07/17/2019, the laboratory did not document a corrective action for the CAP 2018 Event #2 - 80% Potassium (K) scores. 2. The LD, TC, administrative director of lab services, quality and compliance manager, nursing manager, clinical nurse educator confirmed the finding above on 07/17/2019 around 8:15 am. *** Repeat Deficiency*****

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 the review of testing personnel (TP) competency assessment records, proficiency testing (PT) records and interview with the administrative director of lab services, quality and compliance manager, nursing manager, clinical nurse educator, laboratory director (LD) and technical consultant (TC), the TC failed to assess the competency of all (76 of 79) TP through internal blind testing samples or external PT samples in 2017 and 2018. Findings Include: 1. On the day of survey, 07/17/2019, review of TP competency assessment records and PT records revealed the laboratory did not assess test performance of TP through internal blind testing samples or external PT samples for 76 of 79 TP in 2017 and 2018 for Blood gas and Hemoglobin testing performed on the Abbott I-Stat analyzer, EG7+ and EC8+ cartridges. 2. The administrative director of lab services, quality and compliance manager, nursing manager, clinical nurse educator, LD and TC confirmed the finding above on 07/17/2019 around 8:35 am.