Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0657944	03/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pottstown Hospital	1600 E High Street, Pottstown, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing challenge records between 2017 and 2018 and interview with the Administrative Laboratory Director, the laboratory failed to obtain signatures of testing personnel on attestation statement form. Findings include: 1. Review of API proficiency testing challenge attestation form for 2017 Chemistry - Core - 3rd Event, showed 4 of 4 missing signatures for blood gas samples, BG-11, BG-12, BG-13, BG-14, BG-15, BLX-11, BLX-12, BLX-13, BLX-14 and BLX-15. 2. On 03/07/19 at 12:15 PM, administrative laboratory director confirmed the above findings. 3. Laboratory corrected deficiency on-site.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations 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: A. Based on quality control record review and interview with General Supervisor

	(GS) #2, the laboratory failed to include external liquid controls of different concentration for ionized calcium test performed on ABL 80 analyzer on six of six days of patient testing. Findings include: 1. The ionized calcium patient testing was performed on one patient each day of testing as listed: 01/31/19, 02/11/19, 02/25/19, 03/01/19, 03/03/19, 03/05/19. 2. The laboratory could not provide records of external quality control performed on the dates listed above. 3. GS #2 interviewed on 03/06/19 at 11:00 AM stated that the lab performed monthly external quality controls and confirmed the above findings. B. Based on review of quality control records and interview with General Supervisor (GS) #3, the laboratory failed to perform external liquid quality controls (QC) of different concentration, each day of patient testing for Activated Clotting Time (ACT) test analyzed on the Hemochron Signature Elite Jr. analyzer in 2017 and 2018. Findings include: 1. On the days of survey, 03/06/2019, review of ACT quality control records revealed that laboratory performed external quality control for the Hemochron Signature Elite Jr. analyzer on a weekly bases. 2. In 2017, 3 ACT specimen test were performed. 3. In 2018, 5 ACT specimen test were performed. 4. GS #3 confirmed the findings above on 03/07/2019 around 12:30 pm.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations 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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on review of quality control records and interview with General Supervisor (GS) #3, the laboratory failed to include a negative and positive control material, each day of patient testing for Fetal Fibronectin test analyzed on the Hologic Inc. TLi IQ Analyzer in 2017 and 2018. Findings include: 1. On the days of survey, 03/06/2019, review of Fetal Fibronectin quality control records revealed that laboratory performed external quality controls on the Hologic Inc. TLi IQ Analyzer analyzer on every new box or lot number change of the cassettes. 2. In 2017, 2 Fetal Fibronectin specimen tests were performed. 3. In 2018, 14 Fetal Fibronectin specimen tests were performed. 4. GS #3 confirmed the findings above on 03/07/2019 around 12:30 pm. B. Based on review of quality control records and interview with General Supervisor (GS) #3, the laboratory failed include a negative and positive control material, each day of patient testing for Legionella Pneumophilla Serogroup 1 Antigen test performed on the Alere BinaxNOW Legionella Pneumophilla kits in 2017 and 2018. Findings include: 1. On the day of survey, 03/06/2019, review of Legionella Pneumophilla quality control records revealed that laboratory performed a positive and negative control on each new Alere BinaxNOW Legionella Pneumophilla kit and monthly. 2. In 2017, 525 Legionella Pneumophilla specimen tests were performed. 3. In 2018, 562 Legionella Pneumophilla specimen tests were performed. 4. GS #3 confirmed the findings above on 03/07/2019 around 12:30 pm. C. Based on review of quality control records and interview with General Supervisor (GS) #3, the laboratory failed to have quality control procedures for Urine Microscopic analysis examined in 2017 and 2018. Findings include: 1. On the day of survey, 03/06/2019, the laboratory could not provide documentation of daily quality control performed for Urine Microscopic

	analysis in 2017 and 2018. 2. In 2017, 11,172 Urine Microscopic slides were analyzed. 3. In 2018, 10,690 Urine Microscopic slides were analyzed. 4. GS #3 confirmed the findings above on 03/07/2019 around 12:30 pm.
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 record review of Blood Gas Analyzer (ABG) Rapid Point 500 comparison of test results and interview with the Director of Respiratory Care, the laboratory failed to evaluate the relationship between the Rapid Point 500 analyzers (2 of 2) in 2018. Findings: 1. At the time of inspection, the laboratory performed blood gas testing in two locations, Emergency Room and Respiratory Care Unit. 2. Record reviewed at the time of inspection, 03/06/19, revealed the comparison of test results was performed on 02/22/18 and 02/13/19. The laboratory performed one comparison of test results in 2018. 3. In 2018, about 4800 specimens were tested for blood gases. 4. Interview with the Respiratory Care Director and Laboratory Administrative Director at 02:45 PM on 03/06/19, confirmed the above findings.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the CLIA ' s Laboratory Personnel Report (Form CMS-209), review of personnel qualification records, and interview with the Human resources (HR) representative and the laboratory failed to ensure that each individual performing High Complexity testing (1 of 22) is qualified. Refer to D6171
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology

courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on review of the CLIA's Laboratory Personnel Report (Form CMS-209), review of personnel qualification records, and interview with the Human resources (HR) representative and the Vice President & Chief Quality Officer, the laboratory failed to ensure that each individual performing High Complexity testing (1 of 22) is qualified. Findings Include: 1. TP# 20 (Generalist) obtained a Bachelors of Science in Medical Technology from San Juan De Dios College, in the Philippines. 2. On the day of survey, 03/07/2019, the laboratory could not provide documentation of equivalency evaluation of the foreign credentials for high complexity testing personnel (TP) #20. 3. On 03/07/2017 around 12:30pm, the HR representative confirmed a course to

	course evaluation for High complexity TP #20, did not exist at the time of survey.