

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0288878	(X3) Date Survey Completed 01/04/2019
Name of Provider or Supplier Personal Physician Care Pa	Street Address, City, State 4800 Linton Blvd Ste F-103, Delray Beach, FL	
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
D2020	<p>BACTERIOLOGY CFR(s): 493.823(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of API (American Proficiency Institute) proficiency testing records and interview with Testing Personnel # A (TPA), the laboratory failed to get at least 80 % for 2 (3rd event of 2017 and 2018) out of 6 events (1st, 2nd, 3rd testing events in 2017 and 2018) for Bacteriology. Findings included: Review of API proficiency records revealed that the laboratory failed the Bacteriology 3rd event of 2017 and 2018 with a 0 % score for Clostridium difficile Toxin or Antigen giving and overall score of 0 % for Bacteriology. During an interview on 01/04/19 at 2:30 PM, the TPA confirmed that the laboratory failed the events of reference.</p>
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of API (American Proficiency Institute) proficiency testing records and interview with Testing Personnel # A (TPA), the laboratory failed to score at least 80 % for 1 analyte (Sodium) for 1 (1st testing event in 2017) out of 6 events (1st, 2nd, 3rd testing events in 2017 and 2018) reviewed. Findings included: Review of API</p>

proficiency testing (PT) records revealed a score of 60 % for Sodium for the 1st event of 2017. During an interview on 01/04/2019 at 2:30 PM, the TPA confirmed that the laboratory failed the Sodium score for PT.

D3011

FACILITIES
CFR(s): 493.1101(d)

Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

This STANDARD is not met as evidenced by:
Based on observation and interview with the Office Manager, the laboratory stored Oral Glucose Tolerance Beverage in a refrigerator where reagents and patient blood specimens were stored for an undetermined amount of time. Findings Included:
During a tour of the Laboratory on 01/03/19 at 12:45 PM, 10 bottles of Oral Glucose Tolerance Beverage were observed in a refrigerator where reagents and patient blood specimens were stored. (Photographic evidence was obtained). During an interview on 01/03/19 at 2:14 PM the Office Manager confirmed that the Oral Glucose Tolerance Beverage had not been used in at least a year. These were discarded during the tour.

D3037

RETENTION REQUIREMENTS
CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:
Based on review of API (American Proficiency Institute) proficiency testing records and interview with Testing Personnel # A (TPA), the facility failed to maintain documentation of the Laboratory Director or designee's signed attestation for 1 (3rd testing event in 2017) out of 6 events (1st, 2nd, 3rd testing events in 2017 and 2018) reviewed for Bacteriology, failed to retain the raw data from the proficiency testing for 2 (1st and 3rd testing event in 2018) out of 3 testing events (1st, 2nd, and 3rd testing event in 2018) in Bacteriology, and failed to retain the results of Chemistry Core for 1 (2nd testing event in 2018) out of 3 testing events (1st, 2nd, 3rd in 2018) reviewed. Findings included: Review of API proficiency records revealed that the laboratory failed to have documentation of the attestation signed by the Laboratory Director for the 3rd event of Bacteriology of 2017. Review of API proficiency testing documents revealed that the raw data for the Clostridium difficile testing performed in the 1st and 3rd testing event in 2018 was not retained. Review of API proficiency testing documentation revealed the results for the Chemistry Core was not retained for the 2nd testing event in 2018. During an interview on 01/04/2019 at 2:30 PM, the TPA confirmed that the aforementioned documents were not available.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
Based on review of API (American Proficiency Institute) proficiency testing (PT) records and interview with Testing Personnel # A (TPA), the laboratory failed to verify accuracy at least twice a year for the following tests: Parathyroid hormone (PTH), Prostatic Antigen (PSA), Testosterone, 25 Hydroxy Vitamin D, Apolipoprotein A1 and B, Folate, Microalbumin (quantitative), Urine Creatinine (quantitative), Cyanocobalamine (Vitamin B12) for 1 (2017) out of 2 years (2017-2018) reviewed. Findings included: The laboratory was enrolled in PT with API, for the following analyte: Parathyroid hormone (PTH), Prostatic Antigen (PSA), Testosterone, 25 Hydroxy Vitamin D, Apolipoprotein A1 and B, Folate, Microalbumin (quantitative), Urine Creatinine (quantitative), Cyanocobalamine (Vitamin B12) to evaluate twice a year. The laboratory failed to submit the results for the second event of 2017 and there was no documentation of the review of the results. The laboratory also failed Apolipoprotein B 1st event in 2017 with 33 % with no corrective action. During an interview on 01/04/2019 at 2:30 PM, the TPA confirmed that the laboratory failed to submit the results for second event 2017 and had no documentation of the results review, nor for the Apolipoprotein B failure in the 1st event 2017.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:
Based on review of API (American Proficiency Institute) proficiency testing records and interview with Testing Personnel # A (TPA), the laboratory failed to have corrective action for any score less than 100 % for 3 (2nd and 3rd testing event 2017 and 3rd testing event in 2018) out of 6 events (1st, 2nd, and 3rd testing event in 2017 and 2018) reviewed. Findings included: Review of 2nd event 2017 revealed a score of 93% for Endocrinology with no corrective action documentation. Review of 3rd event 2017 for Hematology revealed a score of 86 % with no corrective action documentation. Review of Chemistry 3rd event 2018 revealed a score of 99 % with no corrective action. During an interview on 01/04/19 at 2:30 PM, the TPA confirmed that the laboratory had no documentation of the corrective action for results less than 100 %.

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on observation, record review, and staff interview the laboratory failed to store reagents per manufacturers' instructions (See D5411), failed to document maintenance (See D5431), had expired linearity reagents in use (See D5417), failed to run Quality

	<p>Control daily when performing tests (See D5441), reported patients when Quality Control was not acceptable (See D5481), and failed to follow a Quality Assurance plan (See D5791).</p>
<p>D5411</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on observations and interview with the Office Manager, the laboratory failed to store Linearity controls per manufacturers' instructions for 2 out of 2 years (2017-2018). Findings Included: During a tour of the laboratory on 01/03/19 at 12:45 PM, a box of Linearity for Lipids, Urine/Fluids Chemistry, Immunoassay, General Chemistry, Bilirubin, UIBC, and Vitamin D were observed stored in a freezer (-20 to -25 degrees Celsius). Observation of the boxes revealed they were to be stored at 2-8 degrees Celsius. (Photographic evidence was obtained). The dates of linearity testing and number of patients tested during that time were requested and were not provided. During an interview on 01/03/19 at 1:00 PM, the Office Manager confirmed that the controls were not stored at 2-8 degrees Celsius.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the Office Manager, the laboratory had expired Linearity for Lipids (since 12/01/18) and Linearity for Immunoassay (since 10/24/18). Findings Included: During a tour of the Laboratory on 01/03/19 at 12:45 PM, a box of Linearity for Lipids that expired on 12/01/18 and a box of Linearity for Immunoassay that expired 10/24/18 was observed. (Photographic evidence was obtained). The dates of linearity testing and number of patients tested during that time were requested and were not provided. During an interview on 01/03/19 at 1:00 PM the Office Manager confirmed the boxes were expired.</p>
<p>D5431</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on maintenance records and interview with Testing Personnel #1 (TPA), the laboratory failed to have documentation of the daily maintenance for 6 (July-December 2017) out of 12 months (January-December 2017) reviewed and failed to document every 2 week maintenance and every 2 month maintenance for 2 out of 2 years (2017-2018) reviewed. Findings included: Review of the Cobas e 411 analyzer maintenance records revealed that the following maintenance was required: Daily maintenance- to clean sample/reagent probe and check condensation inside compartment. Weekly maintenance- to clean the sipper probe, incubator and aspiration stations. 2 week maintenance-to clean the rinse station and perform liquid flow cleaning. 2 month maintenance-to replace pinch valve tubing. From July 2017 to December of 2017 there was no documentation of any maintenance performed. From January 2017 to December 2018 there was no documentation of every 2 week or every 2 month maintenance being performed. During an interview on 01/04/19 at 3:30 PM, the TPA confirmed that the laboratory failed to have documentation of the daily maintenance for the period of reference and failed to document every 2 week maintenance and every 2 month maintenance.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
39027 Based on quality control record review for the Cobas e 411, review of proficiency testing samples, and interview with Testing Person #A (TPA), the laboratory failed to run quality controls the same day of the patient testing for 2 out of 2 years reviewed (2017-2018) and failed to run 2 levels of quality control for Clostridium difficile testing since at least 01/02/17. Findings included: Review of quality controls (QC) records for Cobas e 411, revealed that the laboratory on 5/24/2017 ran Free Thyroxine, Free Triiodothyronine, Thyroxine, Testosterone, Total Prostatic Antigen (PSA), Thyroid stimulating hormone (TSH) controls. Then on 5/25/2018 the laboratory ran Proficiency testing samples for Chemistry second event for the hormones of reference and no controls tested on the day for the analytes of reference. Ran QC on 10/17/18 for PSA, Folate, Ferritin, PTH, Vitamin B12, and Vitamin D and ran proficiency testing on 10/18/18. Ran QC on 02/02/18 for Free T3, Free T4, T4, and TSH and ran proficiency on 02/01/18. Ran QC on 05/29/18 for Free T3, Free T4, T4, and TSH and ran proficiency on 05/30/18. Ran QC on 09/04/18 for Free T3, Free T4, T4, and TSH and ran proficiency on 09/05/18. The days of patient testing and number of patients tested were requested and was not provided. During an interview on 01/04/19 at 3:30 PM, the TPA confirmed that the previous Technical Consultant instructed them to run QC the day before testing (patient or proficiency) as long as it was within 24 hours. Manufactures' instructions state that 24 hours only applicable if consecutively ran. The TPA confirmed that the laboratory does not run

24 hours and was shut down at night. New policy (signed by Laboratory Director on 12/2018) stated that QC will be ran and reviewed each day of patient testing. Review of the manufacture's instructions revealed that Clostridium difficile (C. diff) testing was in use 01/02/17 (this is a CLIA Moderately complex test). No documentation of when this test was begun or if it was validated for accuracy prior to implementing was provided. Under Quality Control it states that there are internal controls that "A dotted blue line must be visible in the middle of the reaction window below the C on every Membrane Devise that is tested. The appearance of the blue control dots confirms that the sample and reagents were added correctly, that the reagents were active at the time of performing the assay, and that the sample migrated properly through the Membrane Device. It also confirms the reactivity of the other reagents associated with the assay. A uniform background in the result area is considered an internal negative control. If the test has been performed correctly and reagents are working properly, the background will be white to give a discernible result." Under External QC it states that "The reactivity of the C. diff quik chek complete kit should be verified upon receipt using the positive control and negative control (diluent)." It also states that "Additional tests can be performed with the controls to meet the requirements of local, state, and/or federal regulations and/or accrediting organizations." Patients were performed on 01/27/17, 02/08/17, 03/20/17, 03/27/17, 03/28/17, 04/25/17, 04/28/17, 05/02/17, 05/10/17, 05/17/17, 05/23/17, 05/30/17, 06/01/17, 06/20/17, 06/23/17, 08/10/17, 08/21/17, 10/25/17, 10/26/17, 11/29/17, 01/08/18, 01/17/18, 01/22/18, 02/05/18, 03/01/18, 05/11/18, and 05/21/18. There was no documentation of the internal QC results for each day patients were ran and the only external QC documented was a positive control ran on 05/21/18. During an interview on 01/04/19 at 3:50 PM, TPA stated that she ran QC when opening a new box of tests.

D5481

CONTROL PROCEDURES
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on Integra 400 plus quality control (QC) record review and interview with Testing Person #A (TPA) the laboratory failed to have the 2 levels controls within acceptable range for Total Protein prior to testing patients on 1 testing date (01/31/17) in 2017. Findings included: Review of QC records for Integra 400 plus revealed that on 1/31/17 the 2 levels controls for Total Protein were out of acceptable range. There were no records of any corrective action. On the day of reference, patient 1 and 2 tested and reported. Proficiency testing samples were also tested for that analyte on the same date. During an interview on 01/04/19 at 1:30 PM with the TPA, it was confirmed that there were no records of a rerun for the controls out of range for Total Protein. The TPA also confirmed that patients and proficiency testing samples were ran and reported for that analyte on that day.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The

laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on Quality Assessment (QA) record review, interview with Testing Person #A (TPA), and lack of documentation, the laboratory failed to follow their QA Plan for 2 out of 2 years (2017-2018) reviewed. Findings included: 1. Review of the QA Plan revealed the following forms should be completed: -General Phase Quality Assessment Review Form -Pre Analytical Phase Quality Assessment Review Form - Analytical Phase Quality Assessment Review Form -Post Analytical Phase Quality Assessment review Form -Quality Assessment Review Form -Laboratory Weekly Checklist 2. The QA Plan described additional tasks to be completed quarterly: - January: General Phase (October-December) -April: Pre Analytical Phase (Jan-March) -July: Analytical Phase (April-June) -October: Post Analytical Phase (July-Sept) 3. No documentation for the periodic reviews planned in the QA plan for 2017 and 2018 were present. 4. Review of Laboratory weekly check list records revealed 3 reports for week 1/3/2017, 2/1/2017, 3/28/2017 that were not reviewed nor dated by the Supervisor. There were no other records available for the rest of the weeks of the period 2017 and 2018. 5. The QA Plan did not include review of proficiency testing activity. During an interview on 01/04/19 at 2:30 PM, TPA confirmed that the facility failed to follow the QA Plan for the period of reference.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and interview with the Laboratory Director, the laboratory failed to hire a Technical Consultant that had enough education to qualify for the position for 2 out of 2 years (2017-2018) reviewed (See D6028) and failed to have effective oversight over the laboratory (See D6004).

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Laboratory Director the Laboratory Director failed to effectively oversee the laboratory and the Technical Consultants for

2 out of 2 years (2017-2018). Findings Included: See D5400 for failure to effectively oversee the laboratory. See D6033 for failure to hire qualified Technical Consultants.

D6028

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(10)

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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:

Based on record review and interview with the Laboratory Director, the laboratory failed to hire a Technical Consultant that had enough education to qualify for the position for 2 out of 2 years (2017-2018) reviewed. Findings included: Review of employee files revealed in 2017 and 2018 the laboratory hired a consulting company who provided 2 Medical Technologists (Technical Consultant #B and Technical Consultant #C) to act as Technical Consultants. Technical Consultant #B only had an Associates degree in Applied Sciences for Medical Technology and Technical Consultant #C also had an Associate degree in Applied Sciences for Medical Technology as well as a Bachelor of Science in Health Care Management (not one of the Core Science degrees that would qualify her). These Technical Consultants did not qualify as Technical Consultants per the educational requirements. Review of employee competency records revealed that Technical Consultant #C performed competency evaluations on Testing Person #A and #B on 01/03/17, and Technical Consultant #B performed competency evaluations on Testing Person #A and #B on 06/30/17 and 01/19/18. No competency evaluations were performed on Technical Consultant #B nor #C in 2017 or 2018. During an interview on 01/03/19 at 4:00 PM the Laboratory Director confirmed that the 2 Technical Consultants did not qualify and that he had hired another Technical Consultant at the beginning of December 2018 who did qualify. (Qualification of the the new Technical Consultant #A was confirmed on-site.) The Laboratory Director also confirmed that he did not perform competency evaluations on Technical Consultant #B or #C in 2017 or 2018.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and interview with the Laboratory Director, the laboratory failed to hire a Technical Consultant that had enough education to qualify for the position for 2 out of 2 years (2017-2018) reviewed (See D6035).

D6035

TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) 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; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Laboratory Director, the laboratory failed to hire a Technical Consultant that had enough education to qualify for the position for 2 out of 2 years (2017-2018) reviewed. Findings included: Review of employee files revealed in 2017 and 2018 the laboratory hired a consulting company who provided 2 Medical Technologists (Technical Consultant #B and Technical Consultant #C) to act as Technical Consultants. Technical Consultant #B only had an Associates degree in Applied Sciences for Medical Technology and Technical Consultant #C also had an Associate degree in Applied Sciences for Medical Technology as well as a Bachelor of Science in Health Care Management (not one of the Core Science degrees that would qualify her). These Technical Consultants did not qualify as Technical Consultants per the educational requirements. During an interview on 01/03/19 at 4:00 PM the Laboratory Director confirmed that the 2 Technical Consultants did not qualify and that he had hired another Technical Consultant at the beginning of December 2018 who did qualify. (Qualification of the the new Technical Consultant #A was confirmed on-site.)