

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2091013	(X3) Date Survey Completed 10/04/2023
Name of Provider or Supplier Platinum Management Llc	Street Address, City, State 5250 Auto Club Drive, Suite 170, Dearborn, MI	
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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #2, the laboratory failed to ensure its Hemachron Activated Clotting Time test system's accuracy, precision, and reportable range met performance specifications for 6 (March 2023 to October 2023) of 6 months since the laboratory started testing. Findings include: 1. A review of the laboratory's "Method Validation Plan Policy" revealed a section stating, "For each unmodified FDA-cleared method the laboratory will demonstrate, prior to reporting patient test results that it can obtain the performance specifications for accuracy, precision and reportable range, comparable to those established by the manufacturer. The laboratory will also verify that the manufacturer's reference range is appropriate for the laboratory's patient population." 2. A review of the laboratory's EP Evaluator Simple Precision documentation revealed the laboratory performed its precision study using two levels of quality control materials and performed testing 10 times each on both samples. The range for acceptability of the low control was 135.2 to 187.2. The precision data revealed the sixth run had a result of 131. 3. The surveyor requested corrective action on 10/4/23 at 10:08 am and it was not made available. 4. A review of the "GEM Hemochron 100 ACT Performance Verification Plan" revealed a section stating, "Method Comparison. Whole blood from desired patient population(s) to be tested or spiked samples. Run samples spanning range (minimum 20 samples)</p>

for each assay being verified. Determine acceptance criteria while considering differences in ACT methodologies." 5. A review of the laboratory's EP Evaluator documentation revealed the laboratory had not verified its method against another Activated Clotting Time (ACT) method. 6. A review of the laboratory's "GEM Hemochron 100 ACT Performance Verification Plan" revealed a section stating, "Clinical Decision Targets" stating, "Calculate new targets as compared to the reference method. Minimum of 40 samples required." 7. A review of the laboratory's EP Evaluator documentation revealed a lack of documentation of a minimum of 40 samples tested and a lack of calculated targets. 8. An interview on 10/4/23 at 10:08 am with Testing Personnel #2 revealed the laboratory had used its precision data to establish its accuracy and confirmed the sixth run with the low control was not in range.

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:
. A. Based on record review and lack of documentation, the Technical Consultant was not qualified to perform duties for the laboratory's hematology testing (refer D6035).
B. The Technical Consultant failed to ensure its Hemachron Activated Clotting Time test system's accuracy, precision, and reportable range met performance specifications (refer to D6040).

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 a lack of documentation, the Technical Consultant was not qualified to perform duties for the laboratory's routine chemistry testing for 10 (January 2023 to October 2023) of 10 months the laboratory has been testing in the hematology specialty. Findings include: 1. A review of the laboratory's "GEM Hemochron 100 ACT Performance Verification Plan" revealed the laboratory verified performance specifications of its GEM Hemochron test system on 1/24/23. 2. A review of the Technical Consultant's documentation revealed a lack of at least two years' training or experience in non-waived hematology testing. 2. The surveyor requested documentation of at least two years' training or experience in non-waived hematology testing on 10/4/23 at 9:37 am and it was not made available. 3. The laboratory was given an additional 7 days to provide the missing documentation and it was not provided.

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:

. Based on record review and interview, the Technical Consultant failed to ensure its Hemachron Activated Clotting Time test system's accuracy, precision, and reportable range met performance specifications. Refer to D5421.