Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1018680	07/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Excel Internal Medicine, Inc	513 Brookwood Blvd, Suite 502, Birmingham, AL	

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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) proficiency testing records for 2016 - 2018 (Events #1 and #2), and an interview with the testing personnel, the surveyor determined the laboratory failed to review and evaluate proficiency testing results for Chemistry testing event #2 of 2017. The proficiency testing (PT) records for event #2, 2017, failed to include results from API of the testing event #2 for non-regulated analytes, PSA (Prostate Specific Antigen), Testosterone, and Vitamin D. This affected one of seven testing events reviewed on-site by the surveyor. The findings include: 1. A review of the API proficiency testing records revealed the laboratory failed to obtain/retain the results for the Chemistry testing event #2, 2017 for PSA, Testosterone and Vitamin D, non-regulated analytes, which the laboratory had chosen to enroll with API as a process for verification of accuracy of testing. Due to the laboratory's failure to provide the testing results with the records retained for this event, the surveyor determined the laboratory also failed to document review and evaluation of the testing results. No documented evidence of the review and evaluation was provided to the surveyor. 2. At 10:47 AM, in an interview with the testing personnel and a review of the PT manuals (page by page, twice), testing personnel confirmed the electronic submission record for Chemistry, Event #2 was retained. However, there was no result sheet (record) retained for the event, nor any evidence the laboratory staff had reviewed the results from API to determine accuracy of testing. At 11:00 AM, the results for this event was printed from the electronic system by the office manager.
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 a review of the quality control records for routine Chemistry (Beckman Coulter Access II), instrument printouts with patient data, a review of the manufacturer's assay information sheet, interviews with the testing personnel, laboratory director and technical consultant, and a review of quality assurance reports, the surveyor determined the laboratory failed to ensure at least two levels of quality control were acceptable for Vitamin D on 3/29/17, prior to testing patients and reporting the test results. This affected one day of 4 months of quality control reviewed for 2017. The findings include: 1. A review of the quality control records for routine Chemistry, Vitamin D, revealed on 3/29/17, the low, mid and high levels of quality control (QC), analyzed around 5:45 PM (according to the instrument printouts) were flagged as being outside of acceptable limits. There were no QC limits noted on the instrument printouts. The lot numbers for the QC were identified as #25231, #25232 and #25233 for the three levels of QC. 2. At 11:52 AM, the surveyor requested the testing personnel review the QC record to determine acceptability of quality control. The testing personnel confirmed all three levels were flagged (the acceptable ranges for these lot number were yet to be determined). At this time, the surveyor requested the QC limits corresponding to the lot number of controls tested on the dates in question. The testing personnel provided a sheet of paper with 3 levels /limits handwritten and without the analyte of reference identified. Testing personnel stated this information is kept near the instrument (Access II); and he was told these were the ranges for the analytes for the Access II. Further questions revealed the testing personnel was not aware of manufacturers' assay information sheets or that the QC limits for different analytes may be different. At 12:01 PM, the surveyor requested the manufacturer's assay information sheet for the lot numbers of QC used on 3/29/17 to verify the acceptable ranges for Vitamin D. 3. A review of the instrument data printout for 3/29/17 revealed at least 22 patient specimens were tested for Vitamin D, between 6:50 PM - 8:03 PM, without documentation of repeated and acceptable QC. 4. At 12:38 PM, the surveyor spoke to one of two technical consultants via telephone. The Technical Consultant stated the laboratory did not assay their own quality control per lot number, but instead, utilized the manufacturer's (Biorad) ranges. The TC stated the ranges for the quality control should be posted on a sheet of paper above the instrument each time the lot number changes. The surveyor inquired of the manufacturer's assay information sheet, and was told the sheets should be in a binder in the laboratory. 5. After searching the laboratory, along with the testing personnel, the Biorad assay information sheet was found and included the following information for Vitamin D: Lot #25231, Level I: 12.1 - 23.8 ng/ml Lot #25232, Level II: 25.5 - 43.3 ng/ml Lot #25233, Level III: 82.8 - >120 ng/ml 6. On 3 /29/17, the quality control levels were as follows: Level I = 27 ng/ml, Level II = 61 ng /ml, and Level III =130 ng/ml. 7. The quality assurance report for April of 2017, dated 5/9/17 and signed by the laboratory director, indicated some quality control issues (most controls) for proficiency testing for immunochemistry, specifically for 5/8/17. 8. The laboratory faxed and emailed documents on 7/19/18 and 7/23/18 regarding concerns noted on the survey. In the email, from the office manager is noted: "...Also, for the Vitamin D controls that all 3 levels were out - dated 3/29/2017, and patient testing was still done by Lab tech, patient results were reviewed by Dr. Odi and they

	were clinically okay. The TC saw his deficiency, and was reported on the May 2017 QA along with another issue that occurred in May, but the date of 3/29/17 was wrongly not referenced to in the write up." 9. A review of the May 2017 QA report, revealed the laboratory documented problems with quality control specific to Testosterone, and "for others" After the survey (date not specified), an addendum was added to the QA report: "... Addendum Dates QC were out included 3/29/17 and 4/19 /17." The addendum did not reference Vitamin D. 3/29/17 and 4/19/17 were dates identified on-site by the survey as having quality control failures. These dates had not been referenced in the QA report, prior to the survey. Patricia Watson, BS, MT (ASCP) Licensure and Certification Supervisor