Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2031163	(X3) Date Survey Completed 03/21/2018
Name of Provider or Supplier Ohi West Medical Group Ii Llc	**Street Address, City, State** 1721 Brandon Main St - Ste A, Brandon, 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
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 MLE (Medical Laboratory Evaluation) proficiency attestation sheets and interview with the Assistant Director, the Laboratory Director failed to sign the attestation sheets for three (1st and 2nd 2017 and 3rd 2016) out of six (1st, 2nd, 3rd testing events in 2016 and 2017) testing events reviewed. Findings Included: Review of the attestation sheet for the 1st and 2nd testing event in 2017 and the 3rd testing event in 2016 revealed that the Laboratory Director did not sign the attestation sheet that affirms to the fact that proficiency samples were treated in the same manner as patient specimens. During an interview on 03/21/18 at 12:05 PM, the Assistant Director confirmed that the Laboratory Director failed to sign the attestation statements.
D2121	HEMATOLOGY CFR(s): 493.851(a) 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. This STANDARD is not met as evidenced by: Based on review of MLE (Medical Laboratory Evaluation) proficiency testing results and interview with the Assistant Director, the Laboratory failed to score at least 80% for one (2nd testing event 2016) out of six (1st, 2nd, 3rd testing events in 2016 and

	2017) testing events reviewed. Findings Included: A review of the 2nd testing event in 2016 revealed a score of 66% for White Blood Cell differential. During an interview on 03/21/18 at 12:05 PM, the Assistant Director confirmed the proficiency testing failure.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of records and interview with the Assistant Director the laboratory failed to maintain their quality control records in 2016 and 2017. Findings Included: No records of quality control were available for review for 2016 or 2017. On 03/21/18 at 11:30 AM, the Assistant Director revealed that after their accreditation survey, they shredded all documents of quality control for 2016 and 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 MLE (Medical Laboratory Evaluation) proficiency testing results and interview with the Assistant Director, the Laboratory failed to have corrective action for any score less than 100% for three (2nd 2017, 3rd 2016, and 2nd 2016) out of six (1st, 2nd, 3rd testing events in 2016 and 2017) testing events reviewed. Findings Included: A review of the 2nd testing event in 2017 revealed a score of 98% for Hematology with no corrective action documentation. A review of the 3rd testing event in 2016 revealed a score of 83% for Hematology with no corrective action documentation. A review of the 2nd testing event in 2016 revealed a score of 94% in Hematology with no corrective action documentation. During an interview on 03/21 /18 at 12:05 PM, the Assistant Director confirmed that no corrective action had been documented when the laboratory scored less than 100%.