

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0696902	<b>(X3) Date Survey Completed</b>  09/16/2019
<b>Name of Provider or Supplier</b>  Ohi West Medical Group Llc	<b>Street Address, City, State</b>  700 6th St S, Saint Petersburg, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An unannounced CLIA complaint survey for complaint #2019012907 was conducted at Bayfront Family Health Center on 09/16/2019. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency:
<b>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not have a written procedure for specimens sent to an off-site reference laboratory. Findings included: Record review of the policies and procedures titled: Chorionic Villus Sampling revised 8/5/2016, Loop Eletrosurgical Excision Procedure revised 8/6/2016, Colposcopy revised 8/6/2016, Endometrial Biopsy revised 8/6/2016, and Specimen Labeling revised 10/6/2016 in the laboratory's procedure manual, revealed no written procedure that described the process for sending patient specimens to the off-site reference laboratory for processing and receiving patient results. Interview on 9/16/2019 with the Practice Manager revealed all tissue specimens were shipped to two different reference laboratories (Lab A and Lab B) dependent on patient payer source. Electronic record review of patient history tissue pathology revealed that Patient #2 and #3 had specimens sent to the reference laboratories. Patient #2's tissue specimen was sent 03/06/19 to reference Lab B. On 3/13/2019, the patient history showed "No response- Followup required." The Status section noted "FOLLOWUP" but the</p>

"Action Note" section was blank. The results for Patient #2 were documented as received on 03/28/19. Patient #3's tissue specimen was successfully submitted to reference Lab B on 7/17/2019. On 7/24/2019, the patient history showed "No response- Followup required." The Status section noted "FOLLOWUP" but the "Action Note" section was blank. The results were documented as received on 8/13/2019, but the results were from Lab A and not Lab B where Patient #3's record indicated they were sent. Interview on 09/16/2019 at 12:30 PM with the Practice Manager revealed the staff do not document action taken for the "No response-Followup Required" message received in the patient electronic records. On 09/16/19 at 12:50 PM, the Practice Manager and Residency Program Director stated the laboratory did not have a procedure for sending tissue specimens to an off-site reference laboratory. They stated that the clinic they receive patients from had not provided them with written guidance to ensure patient tissue specimens were sent to the correct off-site reference laboratory.