Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0949371	04/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Watson Clinic Llp	1755 N Florida Ave, Lakeland, 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
D0000	An announced CLIA validation survey was conducted at Watson Clinic LLP on 04/10 /19. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Specific deficiencies cited are as follows:
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with the Clinical Administrator and the Laboratory Director, the laboratory failed to perform competency assessments on 7 out of 13 Testing Personnel (#B, C, D, E, F, G, and H) since 2017. Findings Included: A review of the CMS 209 Laboratory Personnel Report revealed Staff #B, C, D, E, F, G, and H worked at the laboratory as Testing Personnel (TP). A review of personnel records from 2017 - 2019 revealed no competency evaluations were found for TP #B, C, D, E, F, G, and H. Interview on 04/10/19 at 11:55 AM with the Clinical Administrator and Laboratory Director confirmed that there were no competency evaluations on the aforementioned staff.
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 record review and interview with the Clinical Administrator and Laboratory Director, the laboratory failed to document results for positive and negative controls for immunohistochemical stains (MEL A antibody stain, s100 protein antibody, anti - Human Epithelial Antigen Antibody) for 2 out of 2 years reviewed (2017-2019) Findings included: 1. Review of the laboratory's CMS 116 Clinical Laboratory Improvement Amendments Application for Certification revealed that non-waived testing included 3 immunohistochemical stains, Mel A antibody stain, s100 protein antibody stain, and anti - Human Epithelial Antigen (Ber-Ep4) stain. 2. Record review of the quality control logs revealed results for hematoxylin and eosin stains but immunohistochemical stains quality controls were not documented for 2 out of 2 years (2017-2019) 3. Interview on 04/10/19 at 1:30 PM with the Clinical Administrator and Laboratory Director confirmed the laboratory was not documenting positive and negative quality controls for immunohistochemical stains.