Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2024960	03/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ghs/Lab	4360 Fulton Dr Nw, Suite C, Canton, OH	

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
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 interviews with General Supervisor (GS) #2 and testing personnel (TP) #3, the laboratory failed to establish and follow written policies and procedures to assess the competency of two out of three GS's for the highly complex tissue biopsy grossing testing procedures performed based on the responsibilities of the position. Findings Include: 1. Review of the laboratory's Form CMS-209, provided on the date of the inspection, revealed three individuals listed as GS's to include the Laboratory Director as approved, signed, and dated by the Laboratory Director on 03/05/2019. 2. Review of the laboratory's "Histology Competency Testing" policy and procedure, approved, signed and dated by the Laboratory Director and provided on the date of the inspection, did not find any mention of a competency assessment policy and procedure for the assessment of the GS's based on the responsibilities of the position. 3. The Inspector requested the laboratory's GS competency assessment policies and procedures and the laboratory's 2017, 2018 and 2019 GS assessment documentation from GS#2 and TP#3. GS#2 confirmed that the laboratory did not establish and follow a competency assessment policy and procedure for the assessment of the GS, did not assess the GS competencies based on the responsibilities of the position and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 03/12/2019 at 2:54 PM.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)

	At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interviews with General Supervisor (GS) #2 and testing personnel (TP) #3, the laboratory failed to blindly verify 100% (percent) of the tissue biopsy grossing test accuracy verification (TAV) activities performed. Findings Include: 1. Review of the laboratory's "Method of Accuracy" policy and procedure, provided on the date of the inspection, approved via signature and date by the Laboratory Director, did not find any instructions to conduct TAV activities blindly for the tissue biopsy grossing procedures performed. 2. Review of the laboratory's 2018 "Method of Accuracy" log sheets revealed documentation of at least two cases, two times annually that were peer reviewed for tissue description, measurements and number of pieces by TP#1. Documentation of the secondary grossing procedure was indicated and circled on the same log sheet directly below the documentation of the original grossing procedure. 3. The Inspector requested the laboratory's policy and procedure for blind TAV from GS#2 and TP#3. GS#2 and TP#3 confirmed that the laboratory did not establish and follow a policy and procedure for blind TAV activities for the tissue biopsy grossing procedures performed, the TAV activities were not blind and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 03/12/2019 at 3:15 PM.