Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D1020402	08/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Upmc Hillman Cancer Ctr-Camp Hill	101 Erford Road Suite 101, Camp Hill, PA	

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 review of laboratory procedure manuals and interview with testing personnel (TP) #2 and #4, the laboratory failed to establish a procedure to assess the competency of 4 of 5 TP who performed complete blood counts (CBC) and differential smear examinations from 2017 to the date of survey. Findings Include: 1. On the day of survey, 08/13/2019, the laboratory failed to provide a written policy on how to assess the competency of 4 of 5 TP who performed CBC's on the Beckman Coulter AcT diff 2 and read differential smear examinations from 10/25/2017 to 08/13/2019. 2. The laboratory could not provide documentation of competency assessment for TP #4 and TP #5 who performed CBC testing and differential smear examinations from 2017 to 2019. 3. Competency assessment documentation for TP #2 and TP#3 did not include the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples and were not signed by the laboratory director. 4. The laboratory could not provide documentation of semi annual competency assessment for TP #2. 5. TP #2 and #4 confirmed the findings above on 08/13/2019 around 9:58 am.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person.

	This STANDARD is not met as evidenced by: Based on review of records, interview with testing personnel (TP) #2 and #4, the laboratory failed to have a written or electronic request for 68 of 68 patient differential smear examinations ordered by an authorized personnel from 10/25/2017 to the date of survey. Finding Include: 1. On the day of survey, 08/13/2019, the laboratory could not provide test request forms for patient differential smears tests performed from 10 /25/2017 to 08/13/2019. 2. In 2017 (10/25/2017 to 12/31/2017) 10 patient differential smears were examined. 3. In 2018, 53 patient differential smears were examined. 4. In 2019 (01/01/2019 to 08/13/2019) 5 patient differential smears were examined. 5. TP#2 and #4 confirmed the findings above on 08/13/219 around 10:15 am.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the review of the laboratory's procedure manuals, maintenance records and interview with testing personnel (TP) #2 and #4, the laboratory failed to perform calibration and document maintenance activities for 1 of 1 Unico G380 Series microscope used for Mohs microscopic examination from 2017 to the date of survey. Findings Include: 1. On the date of survey, 08/13/2019, review of the laboratory's maintenance records revealed, the laboratory did not document or perform maintenance and calibration on 1 of 1 Unico G380 Series microscope, used for Mohs microscopic examination from 10/25/2017 to 08/13/2019. 2. TP #2 and #4 confirmed the finding above on 08/13/2019 around 10:53 am.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the review of laboratory records and interview with testing personnel (TP) #2 and #4, the laboratory director failed to ensure quality assessment (QA) programs were maintained and documented to assure the quality of laboratory from 2017 to the date of survey. Findings Include: 1. On the day of survey, 08/13/2019, the laboratory could not provide a QA policy from 10/25/2017 to 08/13/2019. 2. The following QA activities provided for the following dates: - January, 2018 to April 2018: assessed but not signed. - May, 2018 and June 2018: not assessed. - July, 2018 to October, 2018: assessed but not signed. - November 2018 to July, 2019: not assessed. 4. TP #2 and #4 confirmed the findings above on 08/13/2019 around 11:05 am.