Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2080543	07/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Platinum Pathology, Llc	10128 West Broad Street, Suite H, Glen Allen, VA	

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 Platinum Pathology, LLC on June 29, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on laboratory tour observations and interviews, the facility's processing room environment failed to provide adequate lighting to safely conduct pre-analytical, analytical, and post-analytical phases of histopathology test processing on the date of the inspection June 29, 2021. Findings include: 1. During a tour of the laboratory on 6 /29/21 at approximately 1:00 PM, the inspector observed and noted the following equipment in use: Sakura Tissue Tek embedding stations (A, B, C), Ventana Benchmark IHC Stainer, four Microtome cutting instruments (Lieca RM2235, Sakura Accu Cut, Reichert-Jung 2030, Leica RM 2035), two Hologic Cytology Processors Thin Prep 2000 (A and B), and 2 Tissue Processors (Sakura Tissue Tek VIP 1 and 2). The inspector was unable to read the equipment serial numbers or reagent expiration labels stored on the bench top without the use of personal cellular flashlight application. The inspector noted eight (8) of ten (10) ceiling lights were not functioning and inquired if the lighting was sufficient for testing personnel to properly identify patient tissue samples' labels/accession numbers. The Senior Vice President of Sales, Marketing & Client Services (SVP) stated on 06/29/21 at approximately 2:00 PM: "I have also noted that it seems very dim." 2. An interview with the SVP (06/29 /21 at approximately 5 PM) and lab director (07/01/21 at approximately 3 PM) confirmed the above findings.

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 a review of policy and procedure manual, lack of documentation, test logs, and an interview, the laboratory director (LD) failed to ensure that histopathology and nongynecologic cytology quality assurance (QA) monitors and audits were maintained per protocol for twelve (12) of 12 months, while reporting thirty-eight thousand six hundred ninety (38,690) patient cases, in calendar year 2020. Findings include: 1. Review of the laboratory's procedure manual revealed a QA policy (Quality Monitor Reporting and Internal Audits), approved by the LD on 11/02/2018, that outlined the actions associated with tracking, trending, and reporting quality monitors related to pre-analytical, analytical, and post-analytical processes for histology and nongynecologic cytology testing performed by the laboratory. The policy stated: "On a monthly basis, all QA monitors are recorded into the Quality Monitors Reporting database. Report will be provided to the Quality Manager at least two days prior to the monthly Quality Management meeting. Annually, a department trending report will be created. Internal audits will be performed on a monthly basis using the Internal Audit Record and will be reviewed by the laboratory manager. The Medical Director is responsible for the overall quality management program." 2. Review of monthly QA reports (timeframe of January 2020 through June 2021) revealed documentation signed by the LD for January 2021 to April 2021. The inspector noted no documentation of quality monitoring reports or internal audit records for calendar year 2020. The inspector inquired and requested to review the QA reports including nongynecologic workload during 2020. The Senior Vice President Sales, Marketing & Client Services (SVP) on 06/29/21 at approximately 4: 00 PM stated: "Our general supervisor performed the audits during the pandemic, but the reports are not available. We have recently made updates for quality metrics and are interviewing for a new general supervisor". 3. Review of the laboratory's patient test logs revealed 38,690 cases were processed in calendar year 2020 (30,514 histopathology, 8,176 nongynecologic cytology) during the lapse in LD reviewed QA audit reports outlined above. 4. An interview with the SVP on 06/29/21 at approximately 5 PM confirmed the above findings.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: A. Based on a review of Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory

	personnel files, and an interview, the technical supervisor (TS) failed to perform the annual competency evaluation for one of four Histopathology testing personnel (HTP) in calendar year 2019. Findings include: 1. Review of the CMS 116 and 209 forms revealed that the laboratory director (LD) identified 4 testing personnel were responsible for high complexity Histopathology testing procedures during the twenty-four (24) months reviewed (June 2019 to June 25, 2021). 2. Review of the laboratory personnel files revealed that HTP #1 lacked a 2019 annual evaluation. (See Personnel Code Sheet). The inspector requested to review a 2019 competency assessment completed by the TS for HTP #1. No record was available for review. 3. An interview with the Senior Vice President Sales, Marketing & Client Services (SVP) on 06/29/21 at approximately 5 PM confirmed the above findings. B. Based on a review of the CMS 116 and 209 forms, laboratory personnel files, and an interview, the TS failed to perform the annual Cytology competency evaluation for one (1) of 1 Cytology Testing Personnel (CTP) in calendar year 2020. Findings include: 1. Review of the CMS 116 and 209 forms revealed that the LD identified one personnel as responsible for high complexity Cytology testing procedures during the 24 months reviewed (June 2019 to June 25, 2021). 2. Review of the laboratory personnel files revealed that CTP #1 lacked a 2020 annual evaluation. (See Personnel Code Sheet.) The inspector requested to review a 2020 competency assessment completed by the TS for CTP #1. No record was available for review. 3. An interview with the SVP at approximately 5 PM confirmed the above findings.