Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0887857	04/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Physicians Immunodiagnostic	512 S Verdugo Dr, Burbank, CA	

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 policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to assess the competency of technical supervisors. The laboratory failed to assess the competency of two of two technical supervisors in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the process to assess the competency of technical supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for two of two technical supervisors during 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 3. During an interview on April 26, 2022 at 10:00 AM, Laboratory Director/Technical Supervisor #1 confirmed these findings.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for

	diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to follow written policies and procedures for an annual statistical evaluation of two of six required gynecologic laboratory statistics. The laboratory failed to document two of six required gynecologic annual statistics for 2020 and 2021. Findings include: 1. The laboratory failed to follow the procedure LABORATORY'S OVERALL STATISTICS AND EVALUATION REPORTS which states: "Statistical evaluation items: - Gyn cases where any rescreen of a normal or neg specimen results in reclassification of LSIL, HSIL, adenocarcinoma or other malignant neoplasms. - Gyn cases where cytology and histology findings are discrepant." 2. The Survey Team requested and the laboratory failed to provide two of six required gynecologic annual statistics for 2020 and 2021. Statistics include: - The number of gynecologic cases where cytology and histology are discrepant - The number of gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms. 3. During an interview on April 26, 2022 at 10:00 AM, Laboratory Director/Technical Supervisor #1 confirmed these findings.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on microscopic review of 387 random negative gynecologic cases/slides and the corresponding final test reports from March 31, 2022 through April 12, 2022 and confirmation by Laboratory Director/Technical Supervisor #1 on April 27, 2022 it was determined that the Technical Supervisor failed to verify the accuracy of one gynecologic cytology test. 1. 22 03561 04/07/2022 ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion and Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory. Scant Cellularity, Obscuring Inflammation LABORATORY DIRECTOR/TECHNICAL SUPERVISOR #1 DIAGNOSIS: Unsatisfactory With Clusters of Inflammatory Cells
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