Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2294971	04/15/2026
Name of Provider or Supplier	**Street Address, City, State**	
Arizona Diagnostic Pathology Associates	3987 E Paradise Falls Dr, Tucson, AZ	

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	Based on a proficiency testing desk review survey performed on April 15, 2026, the laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 C.F.R. 493.803 Condition: Successful Participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the Certification and Survey Enhanced Reporting (CASPER) 155 report and the API-American Proficiency Institute evaluation reports, the laboratory failed to successfully participate in two out of three consecutive testing events for the

	regulated analyte, Progesterone in 2025 and 2026, resulting in an initial unsuccessful performance. Refer to D2107. 1. The laboratory's PT performance was unsatisfactory for the third event of 2025 as indicated below: - Progesterone - 0% 2. The laboratory's PT performance was unsatisfactory for the first event of 2026 as indicated below: - Progesterone - 60%
D2107	ENDOCRINOLOGY CFR(s): 493.843(f) (f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the CASPER 155 report and the American Proficiency Institute (API) Proficiency Testing (PT) records from 2025 and 2026, the laboratory failed to achieve satisfactory performance (80% or greater) for two consecutive testing events for the regulated analyte, Progesterone. Findings include: 1. A review of the CASPER 155 report revealed the following unsatisfactory scores: 2025 event 3, Progesterone 0% 2026 event 1, Progesterone 60% 2. A review of the proficiency testing scores from API. (2025 and 2026) confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of the CASPER-0155 Individual Laboratory Report and American Proficiency Institute (API) 2025 and 2026 records, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of the CASPER-0155 and American Proficiency Institute (API) 2025-3 and 2026-1 evaluation reports, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program.