

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1059073	(X3) Date Survey Completed 07/27/2022
Name of Provider or Supplier Naples Pathology Associates Pa	Street Address, City, State 10200 Arcos Ave Suite 201, Estero, FL	
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 recertification survey was conducted on 7/27/22 at Naples Pathology Associates PA., a clinical laboratory in Estero, Florida. Naples Pathology Associates PA., a is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is a description of the noncompliance.
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Manager, the laboratory failed to ensure quality control (QC) for hematoxylin and eosin (H&E) stains were documented and acceptable before reporting patient results from 04/06/20- 07/25/22. Findings included: Record review of the "Quality Control Chart" logs for hematoxylin and eosin stain revealed no documentation to indicate if the control slides were acceptable or not acceptable for 37 (10/12/20, 03/04/21, 04/12/21, 06/14/21, 07/12/21, 08/29/21, 10/18/21, 01/03/22, 01/10/22, 02/07/22, 02/14/22, 02/28/22, 03/04/22, 03/07/22, 03/11/22, 03/14/22, 03/25/22, 03/28/22, 04/01/22, 04/04/22, 04/08/22, 04/11/22, 04/15/22, 04/18/22, 04/22/25, 04/25/22, 04/29/22, 05/02/22, 05/06/22, 05/07/22, 05/09/22, 05/13/22, 05/16/22, 05/20/22, 05/23/22, 05/27/22, 06/13/22, and 06/17/22) out of 127 days from 04/06/20 through 07/25/22. Review of the laboratory procedure titled Quality Control Slide Procedure and Policy revealed "A control slide is run each day that frozens are prepared and results of the control are documented on the attached Control Slide Log Sheet". On 07/27/33 at 11:10 AM, the Laboratory Manager stated she knew the laboratory had had issues with the pathologist not documenting quality control but thought the issues had been fixed.</p>