Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0683201	11/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Crumay Parnes Associates Inc	1822 Good Hope Rd, Enola, 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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the Clinical Supervisor (CS), the laboratory failed to document the Quality Control (QC) for human chronic gonadotropin (hcG) performed 02/23/2023 to 11/05/2024, using the Consult Diagnostics hCG Urine Tests Cassette. Findings include: 1. The laboratory Quality Control Program policy states," Per package insert, internal controls are included in the test and external controls should be completed with each new lot, each new shipment, monthly as a check on storage, as well as with each new untrained operator." 2. On day of survey 11/05/2024 at 9:20 am, the laboratory could not provide documentation of QC performed for new lot, new shipment, monthly or for new untrained operators when urine hcG examinations were performed from 02/23 /2023 to 11/05/2024. 3. The CS confirmed the findings above on, 11/05/2024 at 9:50 am.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the Clinical Supervisor (CS), the laboratory failed to document the positive and negative control each day of patient testing for KOH and Mineral Oil (Scabies) examinations performed from January 2024 until day of survey. Findings include: 1. The laboratory Quality Control (QC) Program policy states," Control examples are readily available at the microscope for reference. Use of the control should be noted with each read of a specimen." 2. On day of survey 11/05/2024 at 9:20 am review of microbiology logs revealed the laboratory failed to document a positive and negative control each day of patient testing for the following from January 2024 to the date of the survey: - 6 out of 25 days KOH examinations were performed: - 01/1/2024 - 02/06/2024 - 04/03/2024 - 06 /17/2024 - 07/10/2024 - 10/21/2024 -2 out of 3 days Mineral Oil (Scabies) examinations were performed: - 03/13/2024 - 06/13/2024 3. The CS confirmed the findings above on, 11/05/2024 at 9:50 am.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on records, lack of documentation and interview with the Clinical Supervisor (CS), the laboratory director (LD) failed to ensure quality assessment (QA) programs were maintained to assure the quality of laboratory services and to identify failures in quality as they occur from January 2024 to November 2024. Findings include: 1. The laboratory's Quality Assessment Policy stated," The clinical supervisor will review the laboratory records monthly for the following: Patient Test Management, Quality control, Proficiency Testing, Maintenance: Microscope and autoclave, inventory, communications, complaints. The quality factors will be rated as either satisfactory or unsatisfactory on the Quality Assessment form on a monthly basis." 2. On the day of survey 11/5/2024 at 9:10 am, the laboratory failed to provide documentation of the monthly QA Assurance performed for the following: - February 2024 - March 2024 - April 2024 - May 2024 - June 2024 - July 2024 - August 2024 - October 2024 3. The CS confirmed the findings above on, 11/05/2024 at 9:50 am.