| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 39D0907199 | 03/04/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Rma Of Philadelphia | 880 East Swedesford Rd, Wayne, 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 |
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| **D5305** | TEST REQUEST<br>CFR(s): 493.1241(c)<br><br>(c) The laboratory must ensure the test requisition solicits the following information: (c)(1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (c)(2) The patient's name or unique patient identifier. (c)(3) The sex and age or date of birth of the patient. (c)(4) The test(s) to be performed. (c)(5) The source of the specimen, when appropriate. (c)(6) The date and, if appropriate, time of specimen collection. (c)(7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (c)(8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of patient test requisitions and interview with the Laboratory Director (LD), the laboratory failed to include the name and address or other suitable identifiers of the authorized person requesting the test, and/or the laboratory submitting the specimen on 1 of 1 patient test requisition for semen analysis examinations (hematology) reviewed from 2024 to day of survey. Findings Included: 1. On the day of survey, 03/04/2026 at 10:00 am, review of 1 of 1 patient test requisition revealed the laboratory failed to include the name and address or other suitable identifiers of the authorized person requesting the test, and/or the laboratory submitting the speciemen for semen analysis examinations (hematology) performed from 03/04/2024 to day of survey. 2. The LD confirmed the above finding on 03/04 /2026 at 10:30 am. |
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| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, lack of documentation and interview with the Laboratory Director (LD), the laboratory failed to verify the performance specifications for endocrinology tests performed on 1 of 1 Roche Cobas e801 ( s/n 23L1-02) analyzer prior to reporting patient test results from April 2024 to day of survey. 1. The laboratory's Analyzer Verification of Performance policy stated;" The verification of performance process must include: accuracy, precision, reportable range (linearity), and reference interval/range for the laboratory patient population." 2. On the day of the survey, 03/04/2026 at 10:00 am, the laboratory failed to provide documentation for the verification of performance specifications for reference intervals/normal ranges performed for the following analytes tested on 1 of 1 Roche Cobas e801 analyzer before reporting patient results from 04/2024 to 03/04/2026: - Estradiol - Human Chorionic gonadotropin (hCG + Beta) - Luteinizing Hormone (LH) - Progesterone (Prog III) - Follicle-stimulating hormone (FSH B) 3. The laboratory performed 110,915 endocrinology examinations in 2025 (CMS 116, estimated annual volume, dated 03/04/2026) 4. The LD confirmed the findings above on 03/04/2026 at 11:30 am. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory procedure, lack of documentation and interview with the Laboratory Director (LD), the LD failed to follow and maintain the laboratory's established QA program for 1 of 2 years (2025) from 03/04/2024 to 03/04/2026. Findings included: 1. The laboratory's Quality Assurance Plan procedure stated, " Objectives: 7. To review on an annual basis and to update as necessary the Quality Assurance Plan of the laboratory." 2. On day of the survey, 03/04/2026 at 10:00 am the laboratory failed to provide documentation of for the annual review of the the laboratory's Quality Assurance Plan performed for 1 of 2 years (2025) from 03/04 /2024 to 03/04/2026. 3. The LD confirmed the finding above on 03/04/2026 at 11:15 am. |