| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 04D2090071 | 05/24/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Apollo Medical | 111 Cordoba Center, Hot Springs Village, AR | |

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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| **D0000** | . This is the CLIA recertification survey of the Laboratory conducted on 5/24/2018. At the time of recertification survey the laboratory was not in compliance with the following conditions: 42 CFR 493.803(a)(b)(c): Successful Participation 42 CFR 493.807: Reinstatement of Nonwaived Laboratories 42 CFR 493.1215: Hematology 42 CFR 493.1403: Moderate Complexity- Laboratory Director |
| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(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.<br><br>This CONDITION is not met as evidenced by:<br>. Based on a review of the 2017 and 2018 CMS Casper Reports 153D, 155D and the American Proficiency Institute (API) proficiency testing results, it was determined the laboratory had unsuccessful performance in proficiency testing for the tests of White |

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| | Blood Cell (WBC DIFF) Differential, Granulocytes (GRANS), Lymphocytes (LYMPHS), and Monocytes (MONO) as evidenced by: Failure to achieve satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance as cited at D2130. |
| **D2017** | REINSTATEMENT OF NONWAIVED LABORATORIES<br>CFR(s): 493.807(a)(b)<br><br>(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.<br><br>This CONDITION is not met as evidenced by:<br>. Based on review of 2017 and 2018 CMS Casper Reports 155D, 153D, and the American Proficiency Institute (API) proficiency testing results, it was determined the laboratory had a subsequent unsuccessful performance for the test White Blood Cell Differential, Granulocytes, and Monocytes as cited at 2130. |
| **D2130** | HEMATOLOGY<br>CFR(s): 493.851(f)<br><br>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.<br><br>This STANDARD is not met as evidenced by:<br>. A. Based on review of the 2017 and 2018 CMS Casper Reports 155D and 153D, and the American Proficiency Institute proficiency testing results, it was determined the laboratory failed two out of three proficiency testing for the tests of Lymphocytes (LYMPHS) as evidenced by: 1. The laboratory received a score of 40% for the test of LYMPHS in the second proficiency testing event of 2017. 2. The laboratory received a score of 0% for the test of LYMPHS in the first proficiency testing event of 2018. B. Based on the review of the 2017 and 2018 CMS Casper Reports, it was determined the laboratory had three out of three consecutive failures which constitutes unsuccessful performance for the test White Blood Cell Differential (WBC DIFF), Granulocytes (GRANS), and Monocytes (MONO) as evidenced by: 1. The laboratory received a score of 73% for the test of WBC DIFF, 60% for the test of GRANS, and 60% for the test of MONO in the first proficiency testing event of 2017. 2. The laboratory received a score of 33% for the test of WBC DIFF, 20% for the test of GRANS, and 40% for the test of MONO in the second proficiency testing event of |

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| | 2017. 3. The laboratory received a score of 0% for the test of WBC DIFF, 0% for the test of GRANS, and 0% for the test of MONO in the first proficiency testing event of 2018. |
| **D5024** | HEMATOLOGY<br>CFR(s): 493.1215<br><br>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299.<br><br>This CONDITION is not met as evidenced by:<br>. Through a review of proficiency testing records for 2017 and 2018, manufacturer's instruction, temperature records for 2017 and 2018, observations made during a tour of laboratory, Quality Controls records, laboratory policy and procedure manual, patient medical records, lack of documentation, as well as interviews with laboratory staff, it was determined the laboratory failed to meet requirements for Hematology. As evidenced by: D5291: the laboratory failed to prevent recurrence of proficiency testing failures in the general laboratory systems. D5417: laboratory had supplies available for use when they had exceeded their expiration date. D5447: laboratory failed to perform quality control at least once per day when patient specimens were analyzed. D5783: the laboratory failed to document corrective action when QC was outside of the laboratory's established criteria of acceptability. |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.<br><br>This STANDARD is not met as evidenced by:<br>. Through a review of Quality Assessment Plan for Proficiency's testing, Proficiency Testing (PT) records for 2017 and 2018, Plan of Correction from 2017, as well as interviews with staff, it was determined that the Laboratory failed to prevent the recurrence of problems in the General Laboratory Systems. As evidenced by: A. A review of the Laboratory's Quality Assessment Plan for Proficiency Testing (PT) revealed: "Since repeated PT failures can result in cease testing, PT reports should be reviewed promptly upon receipt. This review should identify the causes of any failures for the same test, instrument or range, similar to investigations for out of range QC. A yearly QA review of the entire PT process should assure: 1) PT samples are handled like patient specimens: 2) PT results are reviewed by staff: 3) Corrective action is taken and documented for all PT failures and 4) Correction action is effective in preventing future failures. B. A review of PT records for 2017 and 2018 revealed the laboratory failed White Blood Cell Differential in the first PT event of 2017, second PT event of 2017, and the first PT event of 2018. C. A Proficiency desk review survey was conducted by the State Agency on September 29, 2017 for the first unsuccessful Proficiency Test failure in White Blood Cell Differential. It was noted on the Plan of Correction received on November 11, 2017: " The Laboratory Director is responsible for ensuring all testing personnel successfully participates in |

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| | proficiency testing showing competence in using the analyzer. Laboratory Director is responsible for ensuring a corrective action plan is being followed when unacceptable proficiency testing occurs." D. The Laboratory's Quality Assessment Plan did not prevent recurrence of problems in the first and second proficiency testing event of 2017, or the first proficiency testing event of 2018. E. In an interview on 5/24/2018 at 1230, the technical consultant (as listed on form CMS 209) confirmed the laboratory failed to prevent the recurrence of problems in the General Laboratory System. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.<br><br>This STANDARD is not met as evidenced by:<br>. Through observations made during a tour of the laboratory, as well as interview with staff, it was determined the laboratory had supplies available for use when they had exceeded their expiration date. As evidenced by: A. During a tour of the laboratory on 05/24/2018 at 11:30, the Surveyor observed the following supplies stored in a cabinet within the laboratory: 1. Eight of eight Becton Dickinson (BD) blue stopper vacutainer tubes lot #6216643 with an expiration date of 08/31/2017. 2. Twelve of twelve BD red stopper vacutainer tubes lot # 6160542 with an expiration date of 09/30 /2017. 3. Ninety of ninety BD yellow-red tiger stopper vacutainer tubes lot #6253610 with an expiration date of 03/31/2018. 4. Seventy of seventy BD Culture and Sensitivity Preservation Urine tubes lot # 6216932 with an expiration date of 02/28 /2018. B. In an interview at 1130 on05/24/2018, the technical consultant (as listed on CMS-209) confirmed the supplies had exceeded their expiration dates and were available for use. |
| **D5447** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(i)(g)<br><br>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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>. Through a review of policy and procedure manual, quantative control data for August, October and December of 2017, a review of the Beckman-Coulter patient data logs, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to have documentation of quantative controls for Complete Blood Counts on one of twenty days when patients were tested. As evidence by: A. A review of the policy and procedure manual revealed the "Quality Control Protocol which states quantative controls are run each day of patient testing prior to reporting patient results." B. In a review of August 2018 quantative control printouts and Beckman-Coulter patient data logs, it was determined quantative control was not documented on one of twenty days when patients were tested. Fifteen patients were reported on 08/24/2018 when controls were not documented including patients |

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| | #99002676, patients #99001241, patients #99002740, patients #99002278, patients #99001284, patients #99001197, patients #99002649, patients #99001700, patients #99002222, patients #99002314, patients #99001355, patients #99001200, patients #99002336, patients #99001164, patients #99002747 and patient #99001207. C. . In an interview at 14:00 on 05/24/2018, the technical consultant confirmed there was no documentation of quantative control for August 24, 2018 and that patients were tested. |
| **D5783** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(2)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.<br><br>This STANDARD is not met as evidenced by:<br>. Through a review of Laboratory quality control (QC) policy, Hematology quality control records , lack of documentation and interviews with staff, it was determined the laboratory failed to document all corrective actions when Hematology control data failed to meet the laboratory ' s criteria for acceptability. As evidenced by: A. A review of the Quality control policy revealed the procedure for corrective action which states: "Corrective action is required for any rejected run. Document all corrective action on the remedial action worksheet in the appropriate section." B. A review of Quality Control data for August of 2017, January, March and May of 2018 revealed the Hematology Low Quality Control lot # 0687800 was analyzed seven times on 8/8/2017, and five times on 8/22/17. There was no documentation of corrective action performed on 8/8/2017 or 8/22/17 for Hematology low control level I. C. In an interview on 05/24/2018 at 14:00, the technical consultant (as listed on CMS form 209) confirmed the lack of documented corrective action for Hematology low control level I. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>. Through a review of proficiency testing results, laboratory correction action records, policy and procedure manual, it was determined the laboratory director failed to ensure that corrective action was effective and failed to provide overall management and direction as cited at: D6019: Laboratory director failed to ensure that corrective action was effective in proficiency testing. D6021: laboratory director failed to ensure quality assessment programs are maintained. |
| **D6019** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iv) |

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| | 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.<br><br>This STANDARD is not met as evidenced by:<br>. Based on review of 2017 and 2018 proficiency testing scores, it was determined the laboratory director failed to ensure the correction action followed and was effective for the unsatisfactory performance for the test of White Blood Cell Differential. As Cited at D2130 |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>. Through a review of the quality assessment policy, proficiency testing results, lack of documentation, as well as interviews with staff, it was determined the laboratory director failed to ensure that the quality assessment policies are maintained to assure quality laboratory services as cited at D 5791. |