| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 03D0530411 | 06/28/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Honorhealth Tempe Medical Center | 1500 S Mill Ave, Tempe, 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 |
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| **D5305** | TEST REQUEST<br>CFR(s): 493.1241(c)<br><br>The laboratory must ensure the test requisition solicits the following information: (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. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (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 for frozen section testing performed under the sub-specialty of histopathology and interview with the facility personnel, one out of one pathology test requisitions failed to include the time of specimen collection. Findings include: 1. The laboratory performs frozen section testing under the sub-specialty of histopathology, with an approximate annual test volume of 20. 2. The laboratory's policy titled, Specimen Requisition and Log (PA.003), states, "Examine each specimen and the accompanying requisition for completeness and accuracy... Compare labels on specimen containers with the requisitions. Examine labels to assure that the required information is present. (d.) Date and time specimen was obtained." 3. The pathology test requisition presented for review during the survey for |

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| | patient# TSL-17000021531 for testing performed on 5/31/2018 failed to include the time of specimen collection. 4. The facility personnel confirmed that the time of specimen collection was not listed on the test requisition referenced above. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of quality control (QC) documentation for review and interview with the facility personnel, the laboratory failed to perform and document control procedures using the number and frequency as required for the ROM (Rupture of Membrane) test. Findings include: 1. The laboratory performs ROM testing using the ROM Plus test kit under the specialty of Chemistry, with an approximate annual test volume of 50. On the date of the survey, June 28, 2018, the laboratory's quality control procedure reviewed stated, "External QC will be done with every new lot number, every new shipment and each day of patient testing until IQCP is completed." 2. Review of the ROM test report for patient# 17000603324 indicated the testing occurred on 6/07/18, while QC records reviewed revealed the external QC was last performed on 6/04/18. 3. No QC documentation was provided for review during the survey to indicate the laboratory performed two levels of control material of different concentrations, each day of patient testing as required since January 1, 2016 and as required by laboratory policy. 4. The laboratory presented evidence of an Individualized Quality Control Plan (IQCP) that was performed for the ROM test but the IQCP was not reviewed and approved by laboratory personnel. 5. The facility personnel confirmed that the laboratory did not perform and document controls as required since January 1, 2016 and confirmed that the laboratory had not implemented an Individualized Quality Control Plan (IQCP) for testing performed on the ROM Plus test. |
| **D5775** | COMPARISON OF TEST RESULTS<br>CFR(s): 493.1281(a)(c)<br><br>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on Instrument to Instrument twice yearly comparison studies for two chemistry analyzers (ExL1 and ExL2) that the laboratory utilizes for patient testing and interview with the laboratory personnel, the laboratory failed to indicate the |

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| | acceptability of the difference in values resulted for each analyte tested during the comparison testing performed in March 2018. Findings include: 1. A total of 39 analytes were tested on the each instrument respectively with the testing done using 2 specimens per analyte. 2. The acceptability column on the data log was blank for all 39 analytes. 3. Two laboratory personnel signed off on the data log without any reference to the acceptability of the testing between the two instruments for each analyte. 4. The laboratory personnel acknowledged that the acceptability was not documented. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of patient test reports for frozen section testing performed in the sub-specialty of histopathology and interview with the facility personnel, the laboratory failed to include the correct test date on one out of one test report reviewed during the survey. Findings include: 1. The laboratory performs frozen section testing under the sub-specialty of histopathology, with an approximate annual test volume of 20. The laboratory issues the frozen section diagnosis, which is included on the final test report. 2. One out of one pathology test reports reviewed during the survey (S18-032095 for patient# 17000021531) failed to include the correct test date. The test requisition and pathology report indicated the specimen was collected on 5/31/18, but the frozen section diagnosis included as part of the final test report stated, "Results transmitted to (Physician) at 10:15 am on 5/30/18/HLM". 3. The facility personnel confirmed that the frozen section diagnosis included on the final test report for the patient indicated above listed the incorrect testing date. |