Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0981265	01/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Internal Medicine Of Arizona Pc	4840 E Indian School Road, Ste 101, Phoenix, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of instrument printouts for patient test results generated from the Architect Chemistry analyzer, Horiba Hematology analyzer and Streck ESR (Erythrocyte Sedimentation Rate) analyzer and interview with the facility personnel, the laboratory failed to retain patient test records (instrument printouts) for at least 2 years. Findings include: 1. The laboratory performs patient testing in the specialties of Chemistry and Hematology with an approximate annual test volume of 327,098. The laboratory utilizes the Architect i1000 Chemistry analyzer, Horiba Hematology analyzer, and the Streck ESR analyzer to perform patient testing. Patient test results from the analyzers are electronically interfaced into the Laboratory Information System (LIS), LabDaq. 2. During the survey conducted on January 12, 2022 the surveyor requested the instrument printout from the Architect for testing performed on 12/15/20 for patient# 37820. The laboratory failed to produce evidence of the instrument printout as requested. 3. On 1/12/2022 at approximately 11:50am, the facility personnel interviewed stated that the laboratory failed to retain the instrument printouts for at least two years for patient testing that was performed on the Architect analyzer, Horiba analyzer and the Streck analyzer.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--

	(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. This STANDARD is not met as evidenced by: 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 for the analyte, TSH (Thyroid Stimulating Hormone), using the number and frequency established by the laboratory. Findings include: 1. The laboratory performs TSH testing on patient specimens utilizing the Abbott Architect i1000 analyzer under the specialty of Chemistry. The laboratory's annual test volume for the specialty of Chemistry is 252,234. 2. The laboratory's established policy titled, "Quality Control" presented for review during the survey conducted on 01/12/2022 listed the QC requirement for TSH as follows: Low, Normal and High, each day of patient testing. 3. Review of QC documentation for TSH performed on 08/22/2019 indicated the laboratory failed to perform 3 levels of control material (low, normal, high). QC records reviewed during the survey indicated the high and normal control levels were performed, but no evidence was presented for review to indicate the low level was performed as required by laboratory policy. 4. The number of patients tested for TSH on 08/22/2019 could not be determined at the time of the survey. 5. The facility personnel acknowledged that the laboratory failed to perform three levels of TSH controls on 08/22/2019, as indicated above. .
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the facility personnel, the laboratory failed to include the correct date of specimen testing on the test report generated from the Laboratory Information System (LIS). Findings include: 1. The laboratory performs testing on patient specimens under the specialties of Hematology and Chemistry, with an annual approximate test volume of 327.098. Test results are electronically interfaced into the LIS. Patient test reports are generated from the LIS, which include the date and time of specimen testing. 2. Review of the test report from the LIS for patient# 37820, Acc# 101664 indicated the specimen collection date of 12 /08/2020. The laboratory performed the following tests: CBC, ESR, CMP with Uric Acid, Lipid Panel, Thyroid Profile, Free T3, CRP (high-sensitivity), Urinalysis, Vit D 25-OH, Testosterone, PSA, Ferritin, and SARS-COV-2 IgG. 3. The test report referenced above indicated that all tests were "Run by TRS on 12/15/2020", with test times ranging from 11:50am through 11:53am. 4. At approximately 12:00pm on 1/12 /2022, interview with the facility personnel revealed the testing was performed on 12

	/08/2020, not 12/15/2020. The facility personnel stated that the report was corrected, as evidenced in the Notes Section on the report stating, "Specimen collected 12/08/20, wrong pt. id correct patient is (...), 12/15 TS". The facility personnel stated that the testing personnel corrected the report in the LIS on 12/15/20 causing the LIS to change to specimen run date to 12/15/20. 5. No evidence was presented for review during the survey to indicate the test report contained the correct, original run date for testing performed on the specimen indicated above. 6. The instrument printouts for the testing indicated above could not be produced during the survey. See D3031 for findings. 7. The facility personnel confirmed that the test report referenced above failed to include the correct date of testing.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of patient test records maintained in the LIS, review of the laboratory's Quality Assessment (QA) processes and interview with the facility personnel, the laboratory failed to monitor and identify issues found with corrected test reports, specifically the date of specimen testing listed on corrected test reports maintained in the LIS. Findings include: 1. The laboratory performs testing on patient specimens under the specialties of Hematology and Chemistry, with an annual approximate test volume of 327.098. Test results are electronically interfaced into the LIS. Patient test reports are generated from the LIS, which include the date and time of specimen testing. 2. Review of a corrected test report in the LIS for patient# 37820 failed to include the correct date the testing was performed. The 'test performed' date was changed to the date the test report was corrected. See D5787 for specific findings. 3. Interview with facility personnel on 1/12/2022 at approximately 12:05pm revealed that if a test report needed to be corrected for any reason in the LIS then the date of specimen testing would change to the date of correction by default. The facility personnel stated that it is possible to modify a test result or enter a comment in the LIS without changing the original run date, but the testing personnel who made the correction on the test report indicated above failed to do so. 4. No documentation was presented for review during the survey to indicate the laboratory's QA processes monitored and identified errors associated with maintaining the correct testing date in the LIS on corrected test reports. 5. The facility personnel confirmed that the laboratory's QA processes at the time of the survey failed to monitor and identify issues found with corrected test reports maintained in the LIS.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

	This STANDARD is not met as evidenced by: Based on lack of quality control records for testing performed in the specialty of Chemistry, the technical consultant failed to ensure that the parameters for acceptable levels of analytic performance are maintained throughout the entire testing process. See D5445 for findings.