Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2018895	10/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Riverside Medical Arts	1068 East Riverside Drive, St George, UT	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on quality assessment records review, lack of documentation, and interview with staff, the laboratory failed to verify histopathology frozen section testing by Mohs micrographic surgical techniques at least twice annually for 1 of 2 years of testing (2017). The laboratory performed approximately 83 Mohs surgical frozen sections per year. Findings include: 1. Quality assessment records review failed to include documentation the laboratory verified histopathology specimen collection, preparation, staining and diagnosis by Mohs surgical techniques at least twice annually in 2017. 2. In an interview with staff on Monday the 15th of October 2018, staff confirmed the laboratory failed to document histopathology testing was verified twice annually in 2017. THIS IS A REPEAT DEFICIENCY
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on slide labeling procedure review, Mohs frozen section histopathology slides observed, and interview with staff, the laboratory failed to monitor slide labeling to identify and correct problems identified in the labeling of slides for Mohs case

	specimens with more than one section. The laboratory performed approximately 85 frozen sections per year. Findings include: 1. The laboratory procedure stated the Mohs slides were to be labeled with a Roman numeral for each stage and an Arabic number for each section of the stage with the addition of an alphabetic designation for each slide made for each section within the stage (EX. I for the first stage, 1 for the first section, A for the first slide; I for the first stage, 2 for the second section A for the first slide for that section.) 2. Mohs slides reviewed for case M18-542 labeled slides from stage 1 that had 2 sections I I A...etc and I II A... versus I 1 A... and I 2 A..... 3. In an interview with staff on 10/15/2018 at approximately 10:30 A.M. staff confirmed the slides were not labeled as the procedure stated and that they lacked documentation they followed their pre-analytic quality assessment policy to document they reviewed slides for labeling errors.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by: Based on reagent records review, lack of documentation, direct observation, and interview with staff, the laboratory failed to record the lot number and expiration date for Eosin stain reagent in use between 08/18/2017 and 10/15/2018 and for Potassium Hydroxide (KOH) reagent from 06/2013 to 10/15/2018 to ensure the reagents had not been used after exceeding the expiration date. The laboratory performed approximately 83 histopathology frozen sections per year and 10 KOH tests per year. Findings include: 1. The reagent records log failed to include the date, lot number and expiration date of Eosin reagent in use after the expiration date of 08/18/2017. The most recent Eosin reagent lot number entry recorded was on 12/02/2015, expiring 08 /18/2017. The laboratory failed to record KOH reagents in the reagent record system 2. The Eosin reagent in use on the day of survey was lot number E229-23 with an expiration date of 08/18/2017. The KOH in use on the day of survey was lot number K10604 with an expiration date of 06/2013. 3. In an interview with staff on 10/15 /2018 at approximately 10:45 A.M. staff stated the laboratory failed to have a system to detect reagent expiration dates were monitored to ensure reagents were not used past their expiration date.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on lack of documentation and confirmation by staff, the laboratory failed to

	document they maintained the laboratory microscope for 1 of 2 years reviewed (2017). The laboratory performed approximately 83 frozen section microscopic histology tests per year with an average of 5 slides per section, observed microscopically and approximately 10 Potassium Hydroxide tests per year. Findings include: 1. The laboratory failed to document microscope objective or ocular cleaning, or Kohler illumination centering in 2017. 2. In an interview conducted on 10/15/2018 at approximately 11:30 A.M. staff confirmed microscope maintenance was not documented in 2017.