Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D1106857	06/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lmc-Havasu Regional Medical Center (Ap)	101 Civic Center Lane, Lake Havasu City, 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
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (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 and interview with the facility personnel, the laboratory failed to document the acceptability of staining materials used for testing performed in the sub-specialty of histopathology. Findings include: 1. The laboratory performs the interpretation of pathology specimens and performs frozen sections, including the processing and preliminary interpretation of surgery specimens, when requested. The laboratory's approximate annual test volume is 13,682. 2. No documentation of the H & E stain acceptability was presented for review for frozen section testing that occurred on 2/08/2018 for case# DAC18-1407. 3. The facility personnel confirmed that the laboratory failed to document the H & E stain acceptability on the date indicated above.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for

	diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the facility personnel, the laboratory failed to include one of three required statistics for nongynecologic cytology specimens as part of the annual statistical laboratory evaluation performed during 2016 and 2017. Findings include: 1. No documentation was presented for review during the survey conducted on June 22, 2018 to indicate the laboratory performed an annual statistical laboratory evaluation of the number of patient cases reported by diagnosis, including the number reported as unsatisfactory for diagnostic interpretation, for nongynecologic cytology specimens. 2. The facility personnel confirmed that the laboratory could not produce evidence of the documentation referenced above during the survey. 3. The laboratory's approximate annual test volume for cytology is 1,522.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview with the facility personnel, the laboratory failed to follow established policies with regard to documenting the time spent examining cytology specimens in a 24-hour period. Finding include: 1. The laboratory performs the technical interpretation of non-gynecological cytology specimens, with an approximate annual test volume of 1,522. 2. The laboratory's policy titled, "CYP 3B Maximum Number of Cytology Slides Examined by a Pathologist in a 24-Hour Period" states, "Each pathologist must record time spent each day on primary screening on non-gynecological slides, including FNA direct smears, according to their individual daily workload limit". 3. The workload limit documentation provided for review during the survey conducted on June 22, 2018 indicated the technical supervisor failed to document the time spent examining each non-gynecological case during each 24-hour period for testing that occurred throughout 2016, 2017 and to the date of the survey. 4. The facility personnel confirmed that the cytology technical supervisor was not documenting the time spent examining slides during each 24-hour period.