HCCA

Tulare Regional Medical Center

Mineral King Toxicology Laboratory (MKL) is owned by Tulare Regional Medical Center and managed by HCCA. It is a full service toxicology laboratory offering complete employment and industrial drug testing, forensic drug testing for coroner divisions, law enforcement, attorneys, prisons and other city, state, county and federal agencies in a three county radius. MKL has been providing services to Tulare County for more than 40 years. All aspects of the laboratory have been designed to perform the highest quality testing.

MKL has a pathologist as its Medical Director. The Scientific Director is a pathologist with a PhD in toxicology. The Administrative Director has twenty years of experience directing laboratories. Both toxicologists have bachelor's degrees in science and are licensed by the State of California as forensic alcohol analysts.

MKL is accredited by the College of American Pathologists ("CAP") in forensic drug testing. This is a voluntary, rigorous accreditation that requires biannual inspections by CAP. MKL was last inspected in April of 2015 and reaccredited by CAP. CAP's inspections extend to all areas of the laboratory including policies, procedures, chain of custody, staff training and competency, specimen handling, testing and storage. MKL had to pass approximately 1000 different CAP standards. There are currently only five CAP accredited forensic toxicology labs in California, and there are only forty-six CAP accredited forensic toxicology labs in the entire United States.

MKL voluntarily enrolls in proficiency testing through CAP. MKL is currently enrolled in the following proficiency testing by CAP: Whole Blood Alcohol, Forensic Toxicology, Forensic Urine Drug, and Urine Drug Testing. With proficiency testing, unknown samples are sent to MKL for testing. The results are sent to CAP for grading. If proficiency testing is not graded as acceptable, MKL can lose its accreditation with CAP. MKL has always had acceptable proficiency results

All toxicology runs and quality control are reviewed and signed by MKL's pathologist. Quality control is monitored, and MKL has an accuracy rate of 99.98% for the year of 2015.

Drug confirmation is conducted using a Gas Chromatography/Mass Spectrometry machine (GC/MS), which has quality standards built in to the testing. Quality control is run at the beginning of the testing, after twenty samples, and at the end of testing. If any aspect of the quality control does not pass, the entire run is repeated. We have not had any problem with quality control passing. Results of quality control testing have always matched when we have repeated testing. Split specimens that have been tested by another laboratory and MKL have also always matched in results.

We recently performed a retesting of twenty random specimens that had been tested during the last twelve months. The qualitative results were at 100% for the study. The quantitative results were in excess of the standards deemed acceptable to CAP.

In the case of sample #1505635 our investigation has revealed that this was a single and isolated incident of human error, which has never occurred before in the history of MKL. As described below, MKL has taken steps to insure that it never happens again.

The explanation for what happened with sample #1505635 is as follows:

On June 16, 2015, MKL received a request from the Visalia PD for the testing of a blood specimen of one of its officers for drugs and alcohol. The original blood sample vial had the officer's name on it. On June 18, 2015, that sample was sent through a screening process using Tecan. It came back as "positive" for amphetamines.

Samples can screen as positive for amphetamines for any number of reasons unrelated to the actual presence of amphetamines in the blood, so when samples do screen positive, they are sent for analysis using GC/MS.

Before samples are analyzed in the GC/MS, for confidentiality, partial samples are withdrawn from the original vial and put into a smaller vial, which is identified only by a number.

In this case, the numbered vial was placed into the GC/MS for analysis on June 23, 2015. The GC/MS has spaces for 100 vials (20 rows of 5 spaces each), but in this case only 48 vials were tested.

The vials are loaded into the GC/MS from left to right in each row. The location of each vial is identified in the "Internal Chain of Custody" documentation.

The results of the analysis again showed that the sample was positive for amphetamines, and this was reported to the Visalia PD.

In November of 2015, we received a request from the DA's office that this sample be retested, and that the retesting be done at the DOJ laboratory in Fresno. A portion of the sample was sent to that laboratory.

After the request was made, we retested the sample at MKL and the result was negative for amphetamines. We immediately amended the report that we had given to the Visalia PD.

Our subsequent investigation revealed that the reason for this error was that the vials in that one row were incorrectly loaded into the GC/MS. As a result, the order of the vials in the Internal Chain of Custody was incorrect, and therefore the qualitative analysis of 2 out of the 5 samples in that row was likewise incorrect.

This was the first and only incident of an error in the testing process that we have had in the over 20 years since I have been affiliated with MKL, and I have not heard of any incidents of error prior to then.

To minimize the probability of this occurring again, we have taken certain remedial steps. One is to re-educate all staff involved in the testing process to stress the importance of accuracy in the loading process. Another is to change the way that we number the vials. It will now be done sequentially based upon the date that the specimen first arrives at MKL. By doing this, if a vial is identified out of sequential order, it will be obvious to the person doing the analysis.*

Respectfully submitted this 9th day of February 2016

Sharon Fong CLS

Sharon Fong, CLS
Director of Ancillary Service

* This was not done previously for other reasons, namely because we often test out of sequence for so-called "high profile" specimens to accommodate the Coroner or other governmental agencies. However, in light of the problem, we have decided to adjust our procedures.