

February 14, 2024

To Whom it may concern:

I am the President of Labb, the specifications manufacturer for the UA Series POCTS used with the Pro Reader system. I have developed multiple urine and oral fluid rapid drug test kits in my carreer over the past 26 years. I have worked in the POCT industry since 1997. I have created a number of rapid drug testing certification programs that are in use and recognized by court systems, large corporations and laboratories across the country. I am one of the foremost industry experts on POCT technology, immunoassays, and rapid testing delivery systems.

I understand from one of our clients that you have requested information regarding the use of a Morphine (MOP or MOR) assay and not the use of an Morphine (OPI) assay. This is a common question for non-industry personnel and I understand that it can be confusing. I will attempt to explain the terms and why they are used.

Early on in rapid drug testing, there was only one cut-off level for Morphine. It was a 300 ng/mL threshold. At the time, half of the drug testing industry labled the assay as OPIATES or OPI and the other labeld the assay as MORPHINE or MOR. Some years later, the industry released a 2,000 ng/mL MORPHINE test due to the potential cross reaction issues with Poppy Seed products. When the second cut-off level was established, the industry began to refer to the higher cut-off level of Morphine as OPI and the lower cut-off level of Morphine as MOP. To make things worse, other manufactures ignored this potential standard and came up with a third designation MOR.

Let me be very clear, MOR, MOP, and OPI are the identical assay. All three tests are engineered to detect the exact same calibrators which is Morphine. Opiates is NOT A DRUG. Opiates referes to a drug class. The term OPI is misunderstood by many nonprofessionals and professionals alike. Opiates refers to the following assays:

- 1. Morphine Codeine
- 2. Oxycodone/Oxymorphone
- 3. 6AM / 6MAM (Heiron)
- 4. Hydrocodone/Hydromorphone
- 5. Fentynal
- 6. Tramadol
- 7. Methadone
- 8. Buprenorphine

Of the 8 assays listed above, the OPI, MOR and MOP all detect the drugs listed in the number 1 assay only. Assays 2 through 8 are all opiates that are NOT detected using the OPI, MOR, or MOP assay. There is no difference between a Morphine/Codeine assay labeled as OPI and a Morphine/Codeine assay abled MOR/MOP other than the name printed on the test kit. There may be cut-off level difference through out the market however that does not change the drugs detected by the assay.

A better example may be to look at the Cocaine assay. The industry often uses both 150 ng/mL and 300 ng/mL cut-off levels for this test. Changing the cut-off level for Cocaine assay from 150 to 300 will not change the fact that cocaine is the only drug detected in both cases. It will remain a cocaine test.

I hope this is helpful. If you have any questions, please feel free to send me an email at <u>James@Labb.</u>com and I will do my best to get you the information you require.

Respectfully,

James T Ramsey

President