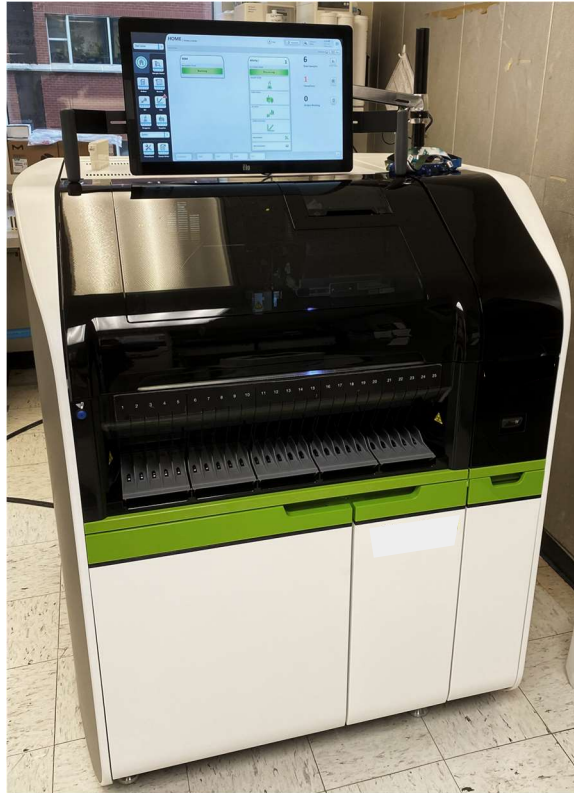


SAFETY MATTERS

Creating a Culture of Safety

April 2024



New Instruments, New Safety Considerations

The HPTN LC Core Laboratory recently acquired a new instrument to replace an existing analyzer.

Part of the process of introduction of the analyzer into the lab involved performing a safety and risk assessment.

This assessment was performed to highlight potential hazards that the introduction of a new analyzer may bring.

This was also a great time to us update our yearly training and safety reviews for staff.

As part of our Quality Management Policy, we have a risk assessment form to aid the assessor(s).

Here is a brief example of what we did and what was determined.

1. Each element was given a numerical risk level, 1 to 4, with 4 being highest risk and high likelihood of occurrence. Protective measures are also assigned to each element; this includes required process changes, focused training, policy/procedure updates, and PPE above the lab baseline to mitigate a hazard.
2. Each risk assessment included observational notes on why a risk was determined to be present or absent, the assigned level, and why the determined protective measures were assigned. These observations included historical lab information, such as number of similar recorded events over the past years -to inform an expected likelihood of comparable events happening.

Example - "SHARPS" Assessment

According to OSHA, sharps are - "objects that can penetrate a worker's skin, such as needles, scalpels, broken glass, capillary tubes and the exposed ends of dental wires."

What we noted:

No Risk - Glass supplies are not used in the routine testing process or sample handling.

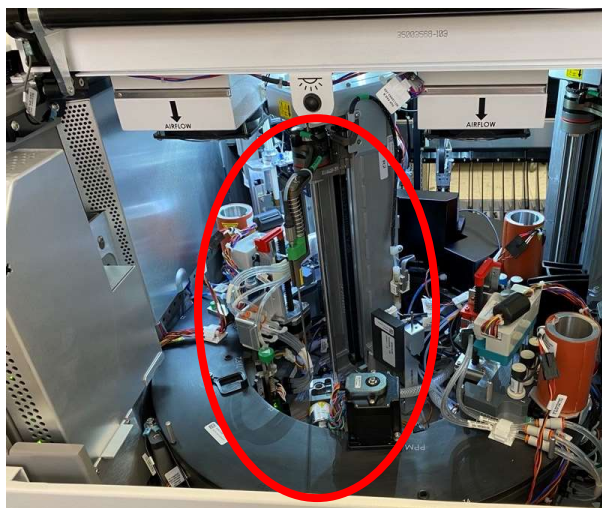
No Risk - Needles or syringes are not used before or after the testing process.

No Risk – New system probes are used during the test process, but are not user accessible during routine operation.

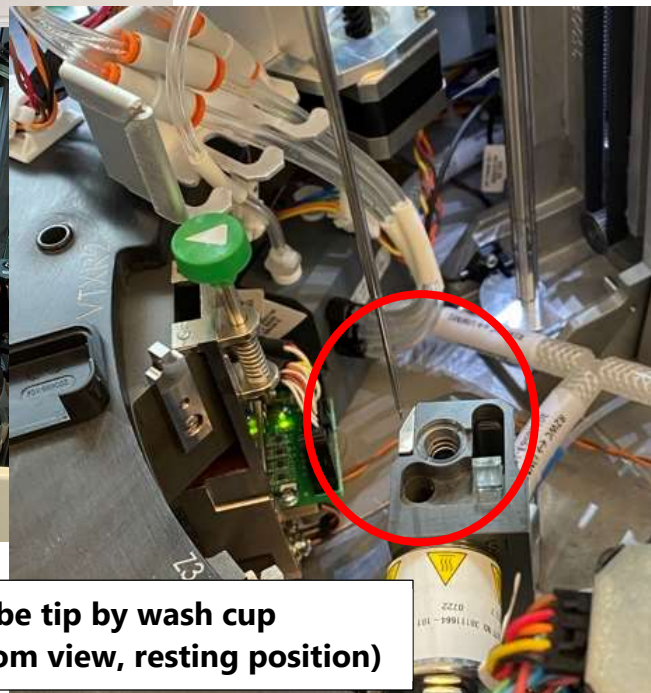
Risk - During routine user performed maintenance or probe changes, the new system probes are exposed and required handling by the user.

We determined that:

When performed properly, there was a minimal risk of puncture from the probes. Accidental puncture could occur if a user was not aware of the location of the probes while performing maintenance tasks. Proper training and following the user manual instructions mitigate this risk.



Three system probes visible (resting positions)



Probe tip by wash cup (zoom view, resting position)

Historic Review:

In the last 5 years of lab operation, there were no reports of sharps or bloodborne pathogen exposure in our lab. This includes instrument maintenance, where users could have been exposed to system probes/sharps.

Conclusion:

Overall risk level was determined as "2" for Minimal Risk.

- There is a definite risk of injury by the analyzer probes during maintenance procedures.
- Risk can be mitigated by training, awareness, and the proper use of PPE.
- This type of injury has not occurred in our lab in the past 5 years.



Practicing What We Preach – GCLP Audit Questions

The introduction of a new analyzer or test system can have implications to your existing safety practices.

Consider the following safety related GCLP audit questions and some responses from the HPTN LC:

Are there procedures available for documenting or reporting safety incidents?

We at the HPTN LC do have a policy for documenting and reviewing safety incidents. This documentation helped us during our recent analyzer safety assessment to show that there were no sharp related injuries within the last 5 years.

Is there a mechanism to evaluate safety incidents?

Yes, we document all safety incidents. We also document if there are no safety incidents. This is reviewed and signed on a regular basis per our Quality Management Plan.

Are SDS readily available to all laboratory personnel?

Yes, all SDS are available and we have performed a review to ensure that that all materials associated with the new analyzer are available.

Is there a written policy for the handling and disposal of biohazardous materials and regulated medical waste?

Yes, and we have reviewed the policy to ensure that it is relevant to the new analyzer system.

Is there evidence of review within a two-year interval of all safety policies and procedures by laboratory management?

Yes, and we have reviewed all safety policies and ensured that they are updated for the new analyzer system.

Is PPE (gloves, gowns, masks/respirators, eye protectors, etc.) available to laboratory personnel?

Yes, and we have performed a review to ensure that the PPE is adequate for the new analyzer system.

Have all laboratory employees (and visitors, if appropriate) been properly trained in the evacuation plan/policy?

Yes, but there is opportunity for improvement. Staff have documented evidence, but company representatives, including service technicians, were only verbally informed of our evacuation plan and shown the posted diagrams in the lab areas. This item will be reviewed by our management team to determine if any processes changes are needed, such as documenting technician acknowledgements.

Are reviews of safe work practices performed and documented at least annually?

Yes, and the safety assessment we performed on the new analyzer system is part of that review.

Reader Poll

On-going reader poll:

- How do you handle safety incident reviews?
 - End of day of occurrence
 - Within 48 hours of occurrence (or report when discovered later)?
 - Weekly discussion at a meeting?
 - Weekly review by one person?
 - Monthly meeting review?

We are still seeking response to our poll from the March issue. We've updated it to a clickable link for the one question. This is anonymous and user information isn't recorded, only responses.

[Reader Poll on Safety Event Reviews](#)

Thank you to all who continue to send feedback about our content!

We are still working to incorporate your suggestions and topics into future safety bulletins.

Need more on a specific topic?

Ideas for upcoming subject matter?

Let us know your thoughts and give feedback at: hptnlc-lab@jhmi.edu