



# MTN-020 LC :

## HIV Testing Case Study and Study Closeout

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Thursday, October 9<sup>th</sup> 2014

# HIV Case Study

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- A clinical research site had some irregular HIV testing results.
- Additional Testing was performed at the MTN Virology Core which revealed some false negative testing results (shown on next Slide).
- This triggered an LC site visit.

# HIV Case Study-Cont.

Study Visit	Site Testing Result	LC Virology Laboratory Result
Month 16	Unigold Negative, Determine Negative	Unigold Positive, HIV RNA = 912 copies/ml
Month 17	Missed Visit	
Month 18	Unigold Positive, Determine Positive	NA

# HIV Case Study-Cont.

Site Practice	Package Insert Direction	Major Concern
<b>Deviation 1: Technician added 2 drops of wash solution</b>	Add 4 drops of wash solution	2 drops of wash may be enough to make the internal control line become positive while not moving the patient sample into the test area.
<b>Deviation 2: Technician used cold wash solution directly from refrigerator</b>	Allow wash solution to come to room temperature for 20 minutes before use	Cold reagent will slow down the test reaction.

# HIV Case Study-Cont.

Observation #	Sample	Drops Wash Solution Added	Wash Solution Temperature	Result 10-12 Minutes (Valid Read Time)	Result Change Post 12 Minutes (Post Valid Read Time)
1	Positive Control	4	Room Temp	Positive	NA
2	Positive Control	4	Cold	Positive	NA
3	Positive Control	2	Room Temp	Positive	NA
4	Positive Control	2	Cold	Positive	NA

# HIV Case Study-Cont.

Observation #	Sample	Drops Wash Solution Added	Wash Solution Temperature	Result 10-12 Minutes (Valid Read Time)	Result Change Post 12 Minutes (Post Valid Read Time)
5	Participant	4	Room Temp	Positive	NA
6	Participant	4	Cold	False Negative	Positive between 12-13 minutes
7	Participant	2	Room Temp	False Negative	No change at 15 minutes
8	Participant	2	Cold	False Negative	Positive at 13 minutes

# HIV Case Study-Conclusions

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- EQA and QC can be 100% successful even while test procedural errors are occurring.
- Procedural errors greatly increase the risk of false negative results in early seroconversion samples or other samples with low antibody titers
- Package insert directions must be followed carefully to maximize performance.