



COMMUNICATION WITH OTHER LABS.

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MTN Regional Meeting
Lab breakout session
Cape Town, SA
October 30, 2013

Western Blot Testing Case Study.

- Lab A sent samples to Lab B for testing.
 - Lab B is the backup for Lab A. The NL was not informed.
- Communication was forwarded to the Serology Department of Lab B.
 - The Supervisor for this section was not aware of MTN- WB kits requirements
- Lab A was informed Non-FDA Approved kits were used.
 - Protocol Deviation was completed and submitted to all Networks.
 - This turned out to be incorrect. The correct kit was in use.

Western Blot Testing Case Study cont.

- MTN Network Lab Representative went to Lab B to verify documentation of the kits used.
 - Lot numbers and Expiration dates were sent to NL- USA.
 - Bio-Rad confirmed the lot numbers were valid for their FDA-approved kits.
- Lab A ended up repeating the WB testing using their own kits.
- The Protocol Deviations were changed to Note To File.

CONTACT NAMES:

- Sites should have a list of contact names for labs where samples are referred for testing.
- Telephone conversations.
- Follow up with e-mails.
 - This serves as a good source.
- Network Lab must be informed of any changes in testing Lab.
 - If it affects Protocol Samples.

Lessons Learned:

- Unnecessary additional work for Lab A.
 - Repeating all the WB's tested by Lab B.
 - Phone calls to Lab B to find out who gave wrong kit information.
 - Protocol Deviation.
- Reputation for Lab B
- NL Representatives in country can assist with communications between labs when needed.
- Phone conversations should be followed with e-mails.