HIV TRI-DOT Discordant Screening Result Investigation and Corrective Actions

Case summary

A tertiary care teaching hospital reported a reactive HIV TRI-DOT screening result in a patient awaiting orthopaedic surgery. An outside laboratory subsequently reported a non-reactive ELISA result, prompting a complaint and an on-site technical investigation.

The investigation identified reported deviations in sample volume, reagent addition and result-reading timing. A repeat HIV TRI-DOT test on the retained serum specimen, performed after centrifugation using a fresh device and the prescribed procedure, was non-reactive with a valid control.

The case illustrates the importance of adherence to the Instructions for Use, appropriate investigation of discordant screening results, and clear separation between a preliminary screening result and a confirmed HIV diagnosis.

Background

HIV TRI-DOT is a rapid visual flow-through immunoassay for the qualitative detection and differentiation of antibodies to HIV-1 and HIV-2 in human serum or plasma. It is a screening assay; an initial reactive result does not, by itself, establish an HIV-positive diagnosis.

Accurate interpretation requires correct specimen handling, adherence to the prescribed reagent sequence and sample volume, and reading the device at the time specified in the applicable Instructions for Use.

The reported incident

On a Saturday evening, a 750-bed tertiary care teaching hospital in western India contacted J. Mitra & Co. Pvt. Ltd. regarding a disputed HIV screening result.

According to the incident account, a patient scheduled for emergency orthopaedic surgery had been screened using HIV TRI-DOT. The result was interpreted as reactive, and the surgical team deferred the procedure.

The patient's family obtained an ELISA test from an outside laboratory, which reported a non-reactive result. The conflicting reports caused distress, and the family threatened legal action against the hospital and the manufacturer.

The Regional Sales Manager referred the complaint to the Product Support Manager for an on-site investigation.

Investigation findings

The Product Support Manager visited the hospital on Sunday morning and reviewed the reported testing procedure with the hospital team.

Reported procedural deviations

The investigation account identified the following departures from the prescribed procedure:

- Two drops of patient specimen were reportedly added instead of the single drop specified in the HIV TRI-DOT procedure.
- Buffer addition after the specimen step was reportedly delayed.
- The device was reportedly interpreted after a delay rather than immediately following completion of the prescribed procedure.

The account also described a faint area of background staining that appeared darker when the device was read later and was interpreted as a reactive dot.

These observations suggested that procedural deviations and delayed interpretation may have contributed to the initial result. However, the account did not establish the precise mechanism responsible for the observed reaction.

Discordant screening results

The reactive HIV TRI-DOT result and the non-reactive outside ELISA result constituted a discordant screening finding requiring further investigation.

Neither result should have been treated in isolation as a definitive determination of the patient's HIV status. Further testing and final interpretation needed to follow the applicable NACO diagnostic algorithm under the supervision of the responsible laboratory clinician.

Surgical decision-making

The reported deferral of emergency surgery required a separate clinical review. A reactive screening result does not establish HIV infection, and HIV status alone should not determine whether an emergency procedure proceeds.

The treating team needed to consider the urgency of surgery, the patient's clinical condition and the risks of delay, while applying standard precautions.

Technical response

Repeat testing

In the presence of the hospital's clinical and laboratory representatives, the Product Support Manager repeated HIV TRI-DOT testing on the retained serum specimen after centrifugation.

A fresh device from the same kit was used, following the prescribed procedure. The repeat result was non-reactive, with a visible control dot and a clear background.

This established the result of the repeat test under the conditions used. It did not independently establish the cause of the original reaction, because specimen processing, device and testing technique had changed together.

Procedural demonstration

The Product Support Manager demonstrated the prescribed testing sequence and illustrated how departures from the procedure could produce abnormal appearances or inconsistent results.

The demonstration supported the training discussion. It should be regarded as an illustration of potential procedural effects rather than definitive proof of the original incident's cause.

Refresher training

A refresher session was conducted for laboratory and casualty technicians covering:

- Correct specimen volume and use of the supplied dropper.
- Prescribed reagent sequence and quantities.
- Allowing each solution to soak into the membrane before adding the next.
- Immediate result reading after completion of the procedure.
- Recognition of control dots, test dots and abnormal background appearances.
- Escalation of reactive or discordant screening results for appropriate further testing.

Incident documentation

According to the original account, the Product Support Manager submitted a written investigation report to the Dean on Monday morning, recording the findings and corrective actions. An apology for the distress associated with the incident was conveyed to the family through the hospital.

Reported outcomes

The original account states that:

- The hospital completed further HIV testing before surgery was performed on Monday.
- The family withdrew its threatened legal action.
- The hospital acknowledged the prompt technical response.
- The hospital requested technician refresher training every six months.

The assays used for further testing, their individual results and the final authorised interpretation should be recorded in the case file. These details are necessary to substantiate the statement that testing followed the applicable NACO algorithm.

The reported continuation of the commercial relationship and subsequent adoption of the company's ELISA products are business outcomes. They do not establish diagnostic performance or validate the investigation's causal conclusions.

Further corrective and preventive actions

In addition to the immediate training response, the following actions are recommended:

1. **Verify operator competency.** Assess technicians through observed testing, including staff working night shifts.
2. **Strengthen the bench procedure.** Make the applicable Instructions for Use readily accessible and clearly specify specimen volume, reagent sequence and result-reading requirements.
3. **Document the diagnostic pathway.** Establish an authorised process for reactive and discordant HIV screening results, including counselling, confidentiality and referral for further testing.
4. **Complete the quality investigation.** Review lot identification, expiry, storage, reagent condition, quality-control records and similar complaints before concluding whether a product-related issue was identified.
5. **Check effectiveness.** Conduct a defined follow-up audit to assess procedural adherence and recurrence. Record the findings before declaring corrective actions effective.

These are recommended follow-up measures; their completion is not established by the incident narrative.

Limitations

This case concerns a single reported incident and is not a clinical performance study.

The available account does not include the original device photograph, contemporaneous timing records, complete laboratory reports, lot-investigation findings or follow-up audit results.

The non-reactive repeat test, performed after centrifugation and with corrected technique, cannot isolate the contribution of individual procedural or specimen-related factors. It also cannot establish lot-wide conformity or justify a general claim about sensitivity or specificity.

Conclusion

The investigation identified reported deviations from the prescribed specimen volume, reagent-addition procedure and result-reading requirements. Repeat testing of the retained specimen after centrifugation, using a fresh device and the prescribed procedure, produced a non-reactive result with a valid control.

These findings suggest that procedural or specimen-related factors may have contributed to the initial result. They do not independently establish the precise root cause or demonstrate that the entire product lot complied with its specifications.

The principal lessons are to follow the applicable Instructions for Use, assess operator competency, investigate discordant screening results through the appropriate diagnostic pathway, and document the effectiveness of corrective actions. Clinical decisions must reflect patient needs and urgency, with a preliminary HIV screening result clearly distinguished from a confirmed diagnosis.