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Unexpected Testosterone Result for External Quality Assessment Scheme Sample

To the Editor:
We would like to report an anecdotal quality assurance incident that looked like a complex problem at first but turned out to be the result of a trivial but significant event.

Our national immunochemistry external quality assessment scheme (EQUAS) initiates six distribution rounds per year, with two freeze-dried samples provided in each round. Although we have previously found good agreement between our results and the national consensus values, during this past year we were faced with a 200–300% increase in testosterone results relative to the consensus, but the samples from rounds 4 and 5 deviated by 200–300%. The problem was therefore traced to these particular samples. A colleague from another laboratory kindly provided us with the round 3, 4, and 5 samples that had been reconstituted in his laboratory. Analysis of these samples produced results that were all within 10% of the consensus value.

Further inquiry into the process of reconstitution of the freeze-dried material did not reveal any extraordinary events that may have contributed to the strange results. However, the laboratory technician responsible for these immunochemistry QC samples reported that he used testosterone supplements for more than a year. Although no problems had arisen during the last year, he realized that during the summer he switched from Sustanon® intramuscular injections to Androgel® gel for skin application. Further temporal analysis revealed a link between the time he switched to the gel and the problems with the testosterone assay. We have to assume that there was some cross-contamination between the Androgel (170 000 nmol/sachet) and the EQUAS sample. Although we know that this particular technician is very hygienic, it appears that it is virtually impossible to completely remove the gel from the hands. This assumption was supported by the observations of Montgomery (1), who showed that five hand washes could not prevent progesterone cream from contaminating a sample through a pipet tip that was picked up bare-handed. In our situation, we believe that during decapping of the EQUAS sample, the gel was transferred to the part of the cap that comes into contact with the sample.

This case clearly shows how an apparently major problem can be traced back to a unforeseen incident and that reconstitution of QC samples is a critical step requiring adequate precautionary measures. In addition, although the incident involved a QC sample, such an event...
could also affect patient specimens, introducing major interpretive problems. The consistent use of disposable gloves is a prerequisite but not a guarantee because they can be contaminated when, for example, the glove finger is pulled from the box, as was observed by Montgomery (1). Avoiding contact between the hands and critical parts of the gloves should be common practice.

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