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Original Article

VERITAS?: A Time for *VERIQAS*™ and a New Approach to Training, Education, and the Quality Assessment of $CD4^+$ T Lymphocyte Counting (I)

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Background: The aim of clinical laboratories is to produce accurate and reproducible results to enable effective and reliable clinical practice and patient management. The standard approach is to use both internal quality control (IQC) and external quality assessment (EQA). IQC serves, in many instances, as a "go, no go" tool to provide real time assurance that instruments and reagent or test systems are performing within defined specifications. EQA however, takes a snapshot at a specific point in time of the full testing process, results are compared to other laboratories performing similar testing but inevitably has some built in delay from sample issue to performance data review. In addition, if IQC or EQA identify areas of concern it can be difficult to determine the exact nature of the problem. In an attempt to address this problem, we have developed an instant QA panel that we have termed *VERIQAS*™, specifically for $CD4^+$ T lymphocyte counting, and have undertaken a "proof of principle" pilot study to examine how the use of *VERIQAS*™ could result in improvement of laboratory performance. In addition, we have examined how this approach could be used as a training and education tool (in a domestic/international setting) and potentially be of value in instrument validation/switch studies (a switch study being defined as a laboratory changing from one method/instrument to a new method/instrument with the *VERIQAS*™ panel being used as an adjunct to their standard switch study protocol).

Methods: The basic panel consists of 20 stabilized samples, with predefined $CD4^+$ T lymphocyte counts, that span low clinically relevant to normal counts, including some blinded replicates (singlet up to quadruplicate combinations). The $CD4^+$ T lymphocyte target values for each specimen is defined as the trimmed mean ± 2 trimmed standard deviations, where the trimmed values are derived from the $CD4^+$ T lymphocyte counts reported by the participating centers (~780 laboratories) that receive each UK NEQAS for Leucocyte Immunophenotyping send out. Results for the *VERIQAS*™ panel were returned online, via a specially designed website, and the participant was provided with an immediate assessment (pass or fail).

Results: To date, the panel has been preliminary trialed by eight laboratories to (i) assess pre-EQA qualification (two laboratories); (ii) address performance issues (two laboratories); or (iii) validate new instruments or techniques (four laboratories). Interestingly, even in this pilot study, the panel has been instrumental in identifying specific technical problems in laboratories with EQA performance issues as well as confirming that implementation of new techniques or instruments have been successful.

Conclusion: We report here a new and novel "proof of principle" pilot study to quality assessment, that we have termed *VERIQAS*™, designed to provide instant feedback on performance. Participating laboratories receive 20 "blinded" samples that are in singlet up to quadruplicate combinations. Once a

Conflict of Interest: The authors declare there are no conflicts of interest. UK NEQAS for Leucocyte Immunophenotyping is a department within the Royal Hallamshire Hospital, Sheffield, England part of the National Health Service for England and Wales and is a not for profit organization. RL, JW, and TD are employees of Immunology Quality Assessment based at Duke University, Durham, North Carolina. Any charges made for *VERIQAS*™ are to recover actual costs for provision of the service. All authors contributed equally to this manuscript.

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centre reports its results via a website, immediate feedback is provided to both the participant and the EQA organizers, enabling, if required, the initiation of targeted remedial action. We have also shown that this approach has the potential to be used as a tool for prequalification, troubleshooting, training and instrument verification. Pilot phase field trials with *VERIQAS*™ have shown that the panel can highlight laboratory performance problems, such as suboptimal instrument set up, pipetting and gating strategies, in a rapid and efficient manner. *VERIQAS*™ will now be introduced, where appropriate, as a second phase study within UK NEQAS for Leucocyte Immunophenotyping to assist those laboratories that have performance issues and also made available to laboratories for training and education of staff and instrument validation studies.

Key terms: CD4; quality control; flow cytometry

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"*VERITAS*" the Roman goddess of truth, daughter of Saturn and mother of virtue is also the Latin for truth. "Truth" is also the guiding force within any laboratory, so as to ensure the provision of accurate and reliable results. This goal is underpinned by the implementation of a comprehensive quality monitoring policy that should include both IQC and EQA. However, providing an effective quality monitoring programme can be a challenge in many areas of testing, for diagnostic or monitoring purposes. We report here a "proof of principle" pilot phase study detailing the development of a novel quality assessment panel, we have termed *VERIQAS*™ (a word combination of "*Veritas*" and "quality assessment studies"), that we believe could be used in EQA performance monitoring, staff training and education and could also used as an adjunct to instrument validation/switch studies.

According to the UNAIDS/WHO global report (www.unaids.org/en/) there are 33.3 million people currently living with the human immunodeficiency virus (HIV), with global projections expecting this to increase further over the next decade (1). In response to these staggering figures, a number of initiatives have been launched to mobilize economic, political and technical capacity in resource limited areas to enable HIV patients to gain access to needed antiretroviral (ARV) medications.

It is now well established that $CD4^+$ T lymphocytes are the primary target for HIV (2), and that it is important to monitor $CD4^+$ T lymphocytes for staging HIV/AIDS disease or, when viral load assays are unavailable, assessing the patients' response (e.g., therapeutic monitoring) to ARV treatment (3,4). Measurement of $CD4^+$ T lymphocytes is usually performed by the use of immunophenotyping and flow cytometric analysis, whereby cells are counted after being labeled with a fluorescently conjugated monoclonal antibody that recognizes a specific surface antigen (e.g., CD3 and CD4) (1). International expansion of $CD4^+$ T lymphocyte testing is underway with many laboratories developing standard operating procedures (SOPs), programmes for training staff and validating testing platforms.

However, there are a number of challenges specific to the introduction and continued monitoring of $CD4^+$ T lymphocytes, including: the remote locations of many laboratories, equipment and personnel validations, and the lack of reference or validation controls similar to those that are available for many routine analytic testing procedures. Now that global laboratory scale up and operational efforts are well underway, additional efforts are required to monitor accuracy and precision of the laboratory parameters being tested. As highlighted, the development of comprehensive IQC and participation in EQA is therefore extremely important (1,5). However, EQA turnaround times from sample issue to data reporting can delay the implementation of changes that are required to improve performance. This delay can impact upon the need for additional staff training or rectification of problems related to equipment/reagent performance (6–8). A study in 2002 showed that laboratories new to participation in EQA programmes have a higher degree of variation from the aggregate mean, when compared to those that have participated in an EQA programme for some time (8). Thus, whilst traditional IQC and EQA methods are crucial in the day-to-day activity of a laboratory they only provide part of the need and they do not, when combined, enable the rapid identification of specific problems. In addition, there is a distinct lack of suitable training material with independently verified target values that can be utilised by instrument manufacturers or national flow cytometry training groups that provides "real time" pass/fail feedback.

The international EQA partnership between the National Institute of Allergy and Infectious Disease—Division of Aids Immunology Quality Assessment Program (DAIDS—IQA) and the UK NEQAS for Leucocyte Immunophenotyping programmes [the latter based within the national health service of England and Wales (a nonprofit-making Government Health Care organization)], have developed,

to address many of the issues discussed earlier, a novel training panel, we have termed *VERIQAS*™, that provides instant verification of competence or performance, of either instrument or individual, using internet based data reporting and analysis. The panel consists of 20 samples (that may consist of either singlet, duplicate, triplicate, or quadruplicate sequences) that spanned a range from very low, clinically relevant to normal $CD4^+$ T lymphocyte levels with target values derived from statistically robust and up to date data from over 780 participating laboratories. Panel results from each of the pilot sites were entered via a specifically designed multilingual website and the involved parties (namely the user and the EQA providers) notified immediately whether the laboratory, or individual, has passed or failed the exercise. We report here the use of the *VERIQAS*™ panel as a "proof of principle" pilot study involving eight international sites and demonstrate how its use has impacted: on staff training and education; its value as a pre-EQA qualification panel; and assisted EQA problem troubleshooting Furthermore, we also show how it has been used as an instrument/technique verification tool in four of these sites and therefore could be a useful tool when undertaking instrument switch studies (a switch study being defined as a laboratory changing from one method/instrument to a new method/instrument with the *VERIQAS*™ panel being used as an adjunct to their standard switch study protocol and not a replacement of their standard protocol). It should be stressed that finalization of any switch study is undertaken with "fresh" patient material because stabilized whole blood, whilst useful for continuous between sample assessment, may differ slightly in composition and performance to fresh patient material.

MATERIALS AND METHODS

Panel Design

The panel comprised of 20 stabilized whole blood samples and was designed such that it could contain single, duplicate, triplicate, and quadruplicate specimen combinations with a range of $CD4^+$ T lymphocyte counts that spanned low clinically relevant to normal counts. The panel samples were obtained from EQA samples that had been stabilized and produced using a previously reported and validated stabilization technique that results in flow cytometric characteristic stability for at least 1 year at 4°C (6,9–13). A minimum of 100 aliquots (over and above the number needed for the UK NEQAS EQA program) were obtained from each sample used by the EQA, thus facilitating a continuous replenishment of the panel—new samples were incorporated into the panel on a rolling 2-month basis (newest replacing oldest).

The $CD4^+$ T lymphocyte target values for each specimen was derived from the EQA results reported by ~780 laboratories participating in each UK NEQAS for Leucocyte Immunophenotyping send out (6). Outliers were removed to provide a trimmed mean ± 2 trimmed standard deviations using the method reported by Healy (14). This validated and widely used statistical EQA data processing method provided an extremely low cost and robust statistical assignment of values for each specimen in the panel and could, if required, be adapted to provide instrument/technique specific target values derived from a large participant data pool. This approach alleviates the need to test each individually prepared specimen at specialist sites inevitably introducing a higher associated testing costs.

The *VERIQAS*™ panel was designed to test the accuracy and precision of $CD4^+$ T lymphocyte analysis. The accuracy was measured by comparing how well the participants results compared to the target mean vale for ach sample within the panel and the precision was measured using the target coefficient of variation (tCV) expected between each duplicated sample group. Accuracy was directly measured by awarding points based on how close they were to a target mean. Thus, 2 points awarded to a result within ±1 SD; 1 point for a result between +1 SD and +2 SD values or −1SD and −2SD values: and 0 (zero) points if the value was outside ±2 SD values. Thus a maximum score attainable for a panel of 20 samples was 40 points. The pass mark was set at 75%, equivalent to 30 points. For monitoring of precision a tCV value of 15% (or below) was assigned to each group of samples (excluding the singlet) for the testing laboratory. Failure to achieve both of these criteria was deemed a fail. The panel design was such that if a laboratory (or individual) had a problem it was much more likely to be identified with the quadruplicate group of samples than on duplicates because the magnitude of error will be magnified with the quadruplicate set of samples. For example, if an acceptable CV for two samples arbitrarily defined as 10% then a corresponding set of four samples would have an acceptable CV of 18.15%. However, by setting a fixed target of 15%, duplicate and triplicate analyses of the panel are less likely to fail whereas it is harder to get all four samples within the 15% defined limit.

Web Site Design

All data derived from the analysis of the samples was returned using a specifically constructed website, www.veriqas.com, currently available in English, French, and Spanish (other languages can be added on request). Each participant was provided with a one time use only password and was required to enter the site using their email address and the password. This approach ensured that the testing-feedback cycle was maintained to enable the maximum benefit to be gained from the testing process. Participants were asked to submit the results obtained (either absolute or percentage values as appropriate) details of instrument used, staining and analysis technique (e.g., whole blood, lyse no wash, CD45 gating). After the data submission an immediate on screen message informed the participant if they had passed or failed the exercise with email confirmation. The mentoring centre (either UK NEQAS or IQA) was also immediately notified with additional information including which sample results fell outside of the target range and what the CVs were for the replicates. If it was deemed appropriate, IQA or UK NEQAS contacted the

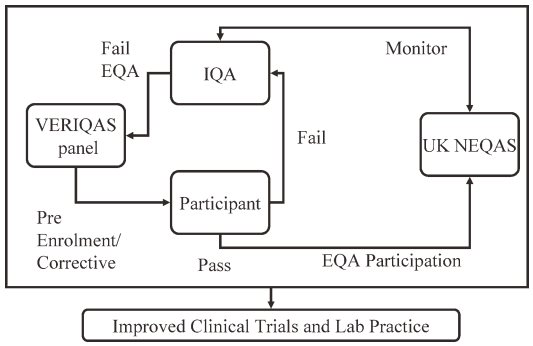

FIG. 1. Schematic flow chart showing how the *VERIQAS*™ is used in pre-EQA enrolment and the EQA monitoring of laboratories within the NIH DAIDS cohort.

participant to discuss results and initiate remedial action. Once remedial action had been undertaken the participant was issued with a new password and they were instructed to retest the panel and submit the results. This cycle continued until the participant achieved a CV of 15% or less on all sample groups and achieved a requisite target pass score for the panel.

Criteria for Issue and Participating Centers

The "proof of principle" pilot study involved eight international centers that have been issued with the *VERIQAS*™ panel where prequalification/troubleshooting EQA issues were identified. The criteria for receiving a panel was based on the following: if a laboratory within the DAIDS/IQA cohort was to be enrolled in the UK NEQAS for Leucocyte Immunophenotyping immune monitoring programme (prequalification); or if during the course of participating in the UK NEQAS programme a DAIDS/IQA laboratory was identified as having persistent unsatisfactory performance that required intervention or training (Fig. 1). The definition of persistent unsatisfactory performance used by UK NEQAS for Leucocyte Immunophenotyping has been described in detail elsewhere (6). The panel was also issued to 2 UK centers for instrument/technique validation prior to its introduction into routine clinical practice. For this "proof of principle" pilot study protocol the use of the *VERIQAS*™ panel was limited to centers which had an immediate EQA problem that had failed to be resolved using conventional means or, as in the case of the 2 UK centers, who specifically requested if they could use the panel as part of the instrument validation/switch studies.

RESULTS

To date, the panel has been issued to 8 international laboratories to enable pre-EQA qualification assessment (two sites), or for instrument/technique validation/switch studies (four sites) as well as to aid laboratories that have known EQA performance issues (two sites), (Table 1).

Laboratories A and B were issued with a *VERIQAS*™ prior to EQA enrolment. Both performed satisfactorily and have no EQA performance concerns at present. Laboratories C and D were issued a *VERIQAS*™ panel because they had been identified as having EQA performance issues following the analysis of their UK

Table 1
Summary of Reasons for Issuing the VERIQAS™ *Panels Showing Country, Reason for Issue and the Subsequent Outcomes*

Laboratory number	Country	Flow cytometer	Gating strategy	Reason for panel issue	EQA performance concerns prior to issue	Intervention provided	Number of times panel tested
A	Malawi	Becton Dickinson FACSCount	Primary CD3 Gating	Pre EQA enrollment	Not applicable	No	1
B	Zimbabwe	Partec CyFlow	CD4/SSC	Pre EQA enrollment	Not applicable	No	1
C	Dominican Republic	Beckman Coulter XL	CD45/SSC	EQA performance concerns	Yes, absolute CD4 counts out of consensus	Yes	3
D	India	Becton Dickinson FACSCalibur	Primary CD3 Gating	EQA performance concerns	Yes, absolute CD4 counts out of consensus	No	1
E	Brazil	Becton Dickinson FACSCalibur	Changed from Primary CD3 Gating to CD45/SSC	New technique introduction	No	No	4
F	Panama	Becton Dickinson FACSCount	Primary CD3 Gating	Existing instrument validation	No	No	3
G	United Kingdom	Beckman Coulter FC500	CD45/SSC	New instrument validation	Not applicable	Yes	2
H	United Kingdom	Beckman Coulter FC500	CD45/SSC	New instrument validation	Not applicable	No	1

NEQAS immune monitoring returns (6). Both these sites received the standard support which included telephone troubleshooting and examination of dot plots/list mode data. Following issue of a *VERIQAS*™ panel, laboratory D rapidly improved their performance and has now no further EQA performance issues. Laboratory C had more fundamental problems and required further intervention involving telephone teaching and examining their standard operating procedures. This approach identified areas of concern such as pipetting, gating strategies and instrument set-up. Figures 2a–2c shows the improvement after each subsequent round of testing of the *VERIQAS*™ panel and EQA review of performance. Note: on Figures 2a–2c the results from each duplicate and quadruplicate sample set are shown adjacent to each other for ease of visualization. In practice each sample was given a random number between 1 and 20 so that the end user could not determine the repeat sequence. Figure 2a shows that on the first attempt no sample (0/20) was within the target range. Laboratory C obtained consistently low values subsequently found to be attributed to pipetting. Once this was addressed, the laboratory tested the panel a second time after being provided with a new "one time only password" and results submitted (Fig. 2b). On this occasion, 6/20 samples were within target range. Interestingly, three of these (Samples 13, 15, and 16) were from a quadruplicate set (Sample 14 being the fourth in the group). The second failure resulted in a more detailed inspection of laboratory practices and remote training was provided (email and telephone conference calls), and this time suggested that instrument set-up was not optimal. Once corrected, the panel was retested without any further intervention from IQA or UK NEQAS. The results (Fig. 2c) were now within the required target range indicating a pass. Subsequently, this laboratory has had no further EQA issues (Fig. 3).

Laboratory E whilst having EQA performance issues for $CD4^+$ T lymphocyte percentages (due to using primary CD3 gating and inadvertently reporting total lymphocyte percentage values derived from $CD3^+$ T lymphocytes) the site, independently (outside of EQA site intervention) decided they would abandon T-gating and switch to CD45/side scatter gating. The laboratory approached us and requested if they could check this switch over using the *VERIQAS*™ panel as an audit procedure in conjunction with their standard switch protocol. The introduction of the new gating strategy resulted in a pass of the *VERIQAS*™ panel and the new approach was adopted as the laboratory's routine practice. No assistance was requested or required from either IQA or UK NEQAS.

Laboratory F (Table 1), whilst having no IQC or EQA issues requested to use the *VERIQAS*™ panel so they could have internal documentation of the instrument validation process as an adjunct to their in-house switch protocol. They were issued with the *VERIQAS*™ panel because whilst having already participated in several rounds of EQA, they had not been through the pre-enrollment process and had not received sufficient samples in the EQA programme to verify performance. The laboratory tested the panel three times without assistance. The first two occasions resulted in a fail due to instrument software issues that were resolved in house. On the third running of the panel, once these issues had been resolved internally, a pass was achieved and the laboratory was cleared to continue with EQA participation without any performance issues. No EQA issues have been subsequently identified.

Laboratories G and H (both UK sites) used the *VERIQAS*™ panel to validate new instruments that were planned to be introduced into routine practice (Table 1). The two sites used the *VERIQAS*™ panel in conjunction with old to new instrument comparative "switch" studies (data not shown). Laboratory G failed the *VERIQAS*™ panel on the first run and the problem was identified as a gating strategy issue after submitting the dot plots to UK NEQAS for examination. It was advised that gate placement was incorrect and once this was implemented the panel was rerun without any further problems. Laboratory H passed the *VERIQAS*™ panel first time to conclude their "switch" studies prior to new instrument introduction.

Following issue of the *VERIQAS*™ panel there have been no ongoing EQA performance concerns for the laboratories that took part in this study.

DISCUSSION

EQA and IQC are a fundamental and vital part of any clinical laboratory testing process. EQA should be coupled with IQC procedures to ensure that the laboratory is able to identify potential problems that may affect their performance. However, the very nature of EQA means that there is usually a delay between sample issue and data analysis. Such a time frame may be unacceptable if a laboratory or EQA organizer already suspects, or knows, that potential problems exist. Often, the easiest route for the laboratory or EQA organizer is to send samples previously issued to the laboratory as these will have known results for the laboratory to retest. But, because the laboratory may have been exposed to these samples previously, it could be possible for the laboratory to identify the samples and ensure their methods provide the correct results and not actually achieve any benefit. In addition, there is also a potential delay in comparing results obtained on the reissue of samples. We therefore, designed a panel, termed *VERIQAS*™ that provides the laboratory a minimum of 20 "blinded" samples, amongst which are singlet, duplicates, triplicates, and quadruplicates. Once results had been entered via a secure website, instant feedback was provided to both the participant and the EQA organizers that enabled the rapid initiation of immediate targeted remedial action.

Our first question was could such an approach have "added value" within an existing EQA system that could benefit the end user and help the EQA provider rationalize, more effectively, staff time for training and education with participating laboratories? The primary drive of any EQA programme should be training and education. An EQA provider should have in place well-defined

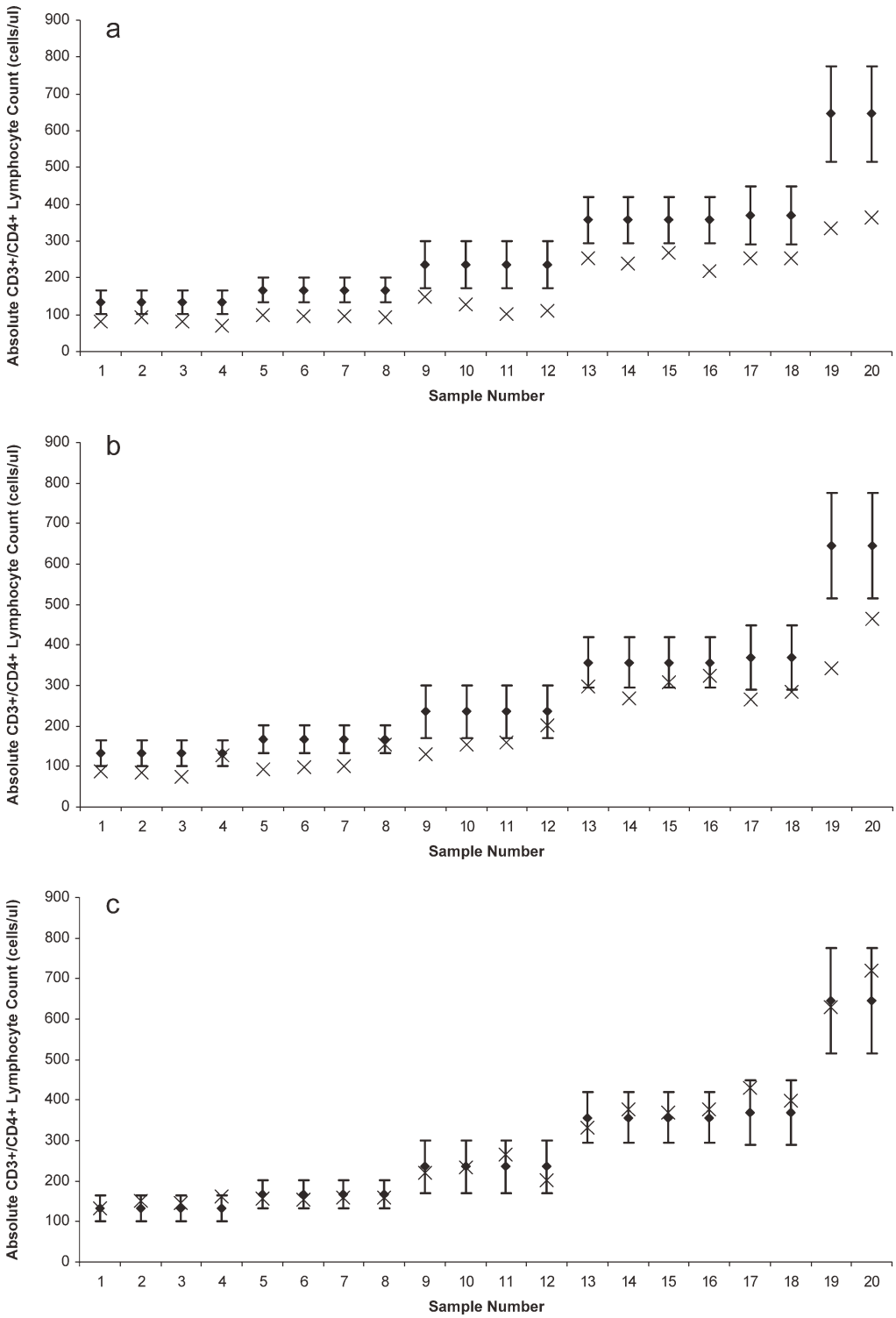

FIG. 2. **(a)** First run of *VERIQAS*™ panel by Laboratory C illustrating that 0/20 values obtained were within the target ranges. Note for this site the panel consisted of two duplicate sets (Samples 17 and 18 and Samples 19 and 207) and four quadruplicate sets (Samples 1, 2, 3, and 4; Samples 5, 6, 7, and 8; Samples 9, 10, 11, and 12; Samples 13, 14, 15, and 16). For the purposes of (**a–c**) and ease of the reader each set of duplicates and quadruplicates the samples are shown next to each other but the samples were randomized when the panel was issued so as to ensure the user could not identify they were replicates. This panel was run on the June 7, 2007. (**b**) Second run of *VERIQAS*™ panel by Laboratory C following the intervention of IQA/UK NEQAS and teaching of pipetting technique. The 6/20 values obtained was within the target ranges. The panel composition was the same as for the first run and completed on the June 14, 2007. (**c**) Third run of *VERIQAS*™ panel by Laboratory C after further remote training (see text) providing advice on instrument set-up. On this occasion 20/20 samples were within the expected target range and no further intervention was required. The panel composition was the same as for the first and second runs and was completed on the June 28, 2007.

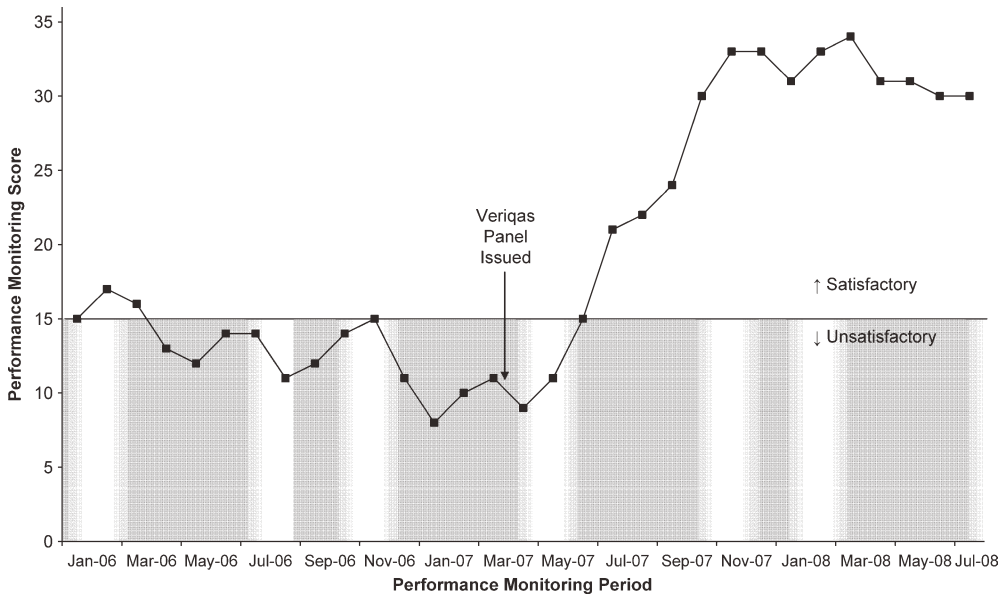

FIG. 3. Performance graph for Laboratory C showing improved and sustained performance in the UK NEQAS immune monitoring programme following the issue of the *VERIQAS*™ panel. Values below the horizontal line denotes where a laboratory is deemed to be having unsatisfactory performance.

assistance mechanisms that enable the EQA provider to enter into dialogue with the participant that should provide insight into the root cause of poor performance. However, this can be a slow process involving numerous communications between the EQA centre and participant. The *VERIQAS*™ panel provides a large amount of information that can be analyzed by trained EQA scientists to pinpoint the exact cause of the problem. It is possible that the panel can also be tailored to specific target values where the participant may be having difficulties. In addition, the issue of the same panel to multiple sites can allow cross site comparison something that cannot be achieved with existing procedures or fresh blood.

The second point is that the system should also be low cost, particularly for laboratories sited in areas where $CD4^+$ T lymphocyte counting is key to providing low cost treatment, such as in sub-Saharan Africa. Such a system should also have the facility to provide rapid feedback to sites outside of the existing EQA programme to which they participate and therefore provide the end user and EQA provider a vehicle to enable rapid intervention and troubleshooting. This is particularly important between send outs as the site will still be issuing results to patients and as EQA send outs are usually every few weeks this approach should also ensure that EQA performance is not compromised and thus provide assurance to the participating laboratory that rapid solutions can be attained.

Finally, whilst such a system should be both rapid and easy to use and be of low cost we felt that the *VERIQAS*™ panel would be of significant value in areas such as individual operator training and as an adjunct (but not replace) "in-house" switch studies. It is important to stress that whilst these issues could be achieved via the flow cytometer manufacturer, or to some degree national flow cytometry societies, the benefit of having "blinded" and stable samples for repeat use is of high importance in areas where such support is limited. Indeed, such panels could be made available to manufacturers and regulatory agencies such as the food and drug administration (FDA) so that they had some training material to use during site visits or in the early stages of instrument design and development.

As EQA providers, we feel it is our duty to offer the *VERIQAS*™ system as part of the ongoing EQA process at no extra cost to the participant because we feel it provides significant added value to the operation of our respective EQA programmes. Thus, UK NEQAS for Leucocyte Immunophenotyping, following approval of our Scientific Steering Committee and National Quality Assurance Advisory Panel (NQAAP) (an independent government and royal college of pathologist oversight body) will provide "free of charge" a panel to all participants within the UK NEQAS programme where EQA performance concerns have been identified as a troubleshooting tool. In addition, laboratories who wish to use the panel for their own purpose outside an EQA environment (staff training or as part of an internal method/instrument switch study) will be able to purchase the *VERIQAS*™ panel for a small charge, currently of £75 per panel.

The development of the *VERIQAS*™ system and the initial results of this pilot phase study has shown that not only is immediate assessment of laboratory performance achievable but the use of such a system also provides a pre-qualification, and tool, troubleshooting, and a training and instrument verification tool. Preliminary field trials with *VERIQAS*™ have shown that the use of this panel assists the identification of problems, such as pipetting and gating strategies, that affect how a laboratory performs in the early stages of EQA participation (8),

allowing UK NEQAS and IQA to initiate remedial action accordingly. It also enables a laboratory to adjust to an EQA programme earlier and thus not "contaminate" the database as previously reported (8). In addition, our studies have shown that the use of the *VERIQAS*™ panel contributes to resolving problems identified during the EQA send outs (Figs. 2a–2c). Indeed, where the *VERIQAS*™ panel has been used to identify technical problems there has been an immediate and sustained improvement of laboratory performance in relation to ongoing EQA.

The approach described here is unique and simple, and is easy to implement, whilst this study only involves eight laboratories, initially results and responses from laboratories have been positive and thus, as mentioned earlier, the panel will be rolled out for use in EQA studies where EQA performance issues are of concern and that cannot be resolved by traditional approaches. As the panel utilizes excess material normally produced during EQA specimen production the cost of production is therefore low and means that there will always be panels available to use if required. One added benefit of the *VERIQAS*™ panel is that the target values for absolute counts and percentage values are well estimated since they are derived from the results reported by a large number of laboratories (>780) that assayed the same stabilized specimen, rather than using single site laboratories. In addition, due to the high number of data sets used to generate the target values it is relatively simple to generate an instrument/technique specific panel. Thus, if a laboratory or instrument manufacturer wishes to evaluate a new technique or instrument it can use the *VERIQAS*™ panel with defined instrument specific target values and have immediate compliance testing. One further aspect of this unique approach is that the panel can also be used to assess linearity of the test/instrument (15). This is an approach that is currently being evaluated internally before roll out. Finally, whilst this approach has described the utility of *VERIQAS*™ in $CD4^+$ T lymphocyte counting the approach can be easily used to evaluate other lymphocyte subsets, stem cell enumeration and low level leucocyte counting. Indeed, the approach can be utilized for any laboratory test where quantitative/qualitative data is being used and in which stabilized blood has been shown to be a good first step towards identifying technical problems. Identification of technical and procedural problems in a rapid and efficient manner ensures that laboratories can provide a reliable and effective clinical service and thus rectify the problematic issues rapidly that may impact on this process. Future studies are planned to examine its utility in blood coagulation studies such as INR testing where stable material can be issued with known target values.

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