Implementation of a strategy for improving the serological diagnosis of HIV/AIDS by introducing the internal quality control

Implantação de estratégia para a melhoria do diagnóstico sorológico de infecção por HIV/AIDS pela introdução de controle de qualidade interno

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RESUMO
No presente estudo estão descritos os resultados das primeiras análises feitas quanto ao desempenho das unidades componentes da Rede de Laboratórios de Diagnóstico de HIV/AIDS do Estado de São Paulo, que concordaram em participar da implantação do controle de qualidade interno para o diagnóstico sorológico da infecção pelo HIV (CQI-HIV) nos respectivos serviços referentes à detecção de anticorpos anti-HIV. De abril de 2009 a fevereiro de 2010 foram distribuídos os painéis de soro CQI-HIV para 37 laboratórios da sub-rede do Estado de São Paulo. Desses, 27 (73,0%) enviaram ao IAL Central os formulários com os resultados obtidos no CQI-HIV para EIA/ELISA. Entre os 22 (59,5%) laboratórios que realizam também o ensaio de IFI HIV-1 na rotina diagnóstica, 11 (50,0%) executaram o sistema CQI para esse teste. Em vista dos laboratórios participantes terem apresentado idênticos dados na determinação de reatividade ideal das amostras do painel para os conjuntos diagnósticos procedentes de mesmas firmas produtoras e de diferentes lotes, pode-se inferir que os laboratórios seguiram os procedimentos preconizados, o que demonstra a adequada execução da conduta padronizada. Ademais, a análise dos resultados obtidos indica que os conjuntos diagnósticos utilizados pela rede de laboratórios são de boa qualidade e de boa reprodutibilidade.
Palavras-chave. controle de qualidade, infecção HIV, sorodiagnóstico AIDS, anticorpos anti-HIV.

ABSTRACT
The present study reports the data resulted from the first evaluation on the performance of the laboratory units of the HIV/AIDS Diagnosis Laboratory Network of the State of São Paulo, which have agreed to participate in the Internal Quality Control scheme for HIV antibody testing (HIV-IQC) at the respective routine diagnostic services. From April 2009 to February 2010, the HIV-IQC serum panels were distributed to 37 laboratories of the Sub-Network of São Paulo State. Of these, 27 (73.0%) sent the forms back to the IAL-Central Lab with the achieved results from the IQC in HIV EIA/ELISA kits. Among 22 (59.5%) laboratories, which perform additional HIV antibody testing by indirect immunofluorescence-based assay (HIV-IFA), 11 (50.0%) carried out the HIV-IFA IQC. As identical data were reported from procedures by employing the IQC samples in different batches of EIA/ELISA kits from the same manufacturers, it may inferred that the laboratories have complied with the recommended procedures, and that the standardized conduct has been followed. Furthermore, the analyses on reported results indicated that the majority of commercial diagnostic kits used for routine HIV antibody testing at the Network laboratories show good quality and reproducibility.
Key words. quality control, HIV infection, AIDS serodiagnosis, anti-HIV antibodies.

INTRODUCTION

HIV infection and AIDS have currently been diagnosed by means of laboratory methodologies for determining the circulating anti-HIV antibodies (HIV Ab testing), the circulating HIV antigens, the related immunologic markers, HIV viral load, HIV DNA PCR, HIV genotyping, drug resistance, HIV presumptive recent infection assay[1-6], and in Brazil these tests have been conducted by specific Laboratory Networks, being the HIV Ab testing Network the largest one, mainly in São Paulo State.

At any of these strategies, the HIV Ab testing laboratory network faces a primary challenge over the quality control issue. The excellence in the analytical quality of the employed diagnostic reagent kits and the accurate performance of serology tests are critical for producing high quality laboratory outcome. Thereby, the quality system implementation is a highly relevant strategy and it is demanded at all of laboratory units that carry out any activities linked to HIV/AIDS programs[7].

The Brazilian Ministry of Health defined and regulated the Laboratory Sub-Network linked to the National Bureau for STD, AIDS and viral hepatitis, and the Analytical Quality Control Program for HIV Diagnostic Laboratory (HIV AQCP) was established, through Decree 59 MS/GM of January 28th 2003[8], having in mind to implement the specific actions for improving upon and to guarantee the laboratory diagnoses quality.

The HIV AQCP focused on holding Technical Training Workshops for the public regional and municipal reference laboratory network of the São Paulo State, which was designed to provide technical skills to laboratory professionals in setting up the São Paulo State quality scheme to monitor the analytical variations in HIV antibodies serologic assays performance[9].

Being the Internal Quality assessment scheme one of the requisites for evaluating the laboratories of State Sub-Network, the use of this strategy by the State Reference Laboratory (IAL-Central Lab) has turned feasible to qualify them for conducting HIV AQCP, aiming at increasing awareness of the quality of results generated from laboratory testing.

In order to assess the serologic tests performance whether the results are within the pre-defined tolerance limits, an appropriate QC sample should be included in every test run, in conjunction with patients' samples in analysis and control samples inserted in the commercial test kits in use. HIV positive internal control samples should be individually titrated at each laboratory and by each laboratory, and these serum samples panels used for monitoring the assays performances are named IQC[3,7,10-13].

The present study reports the formally approved procedures and the specific activities developed for accomplishing the HIV IQC implementation steps, and the data generated from the first analyses done on performance of participant units of the HIV/AIDS Diagnostic Laboratory Network of the São Paulo State.

PROJECT APPROACH/METHODS

Organization and structure of internal quality control system

For subjecting to regulation the use of plasma samples discarded by blood screening laboratory center and to be donated for being employed as sera source to prepare samples panels, the IAL-Central Lab wrote up a guideline outlining the procedures for standardizing and organizing the transfer flow of plasma bags from hemotherapy service network, and for the processed product to be available to the HIV Diagnostic Laboratory Network of São Paulo State. These procedures were written down in compliance with effective legislation criteria and sanitary authority approval for exclusive use of donated plasmas for producing IQC serum samples for HIV Ab testing in São Paulo State. Under these circumstances, a team-work was instituted by Resolution SS-94/2006[14], for standardizing the pertinent technical and administrative procedures. This group was comprised of professionals linked to the Diseases Control Coordination (including Instituto Adolfo Lutz-Central Lab – IAL, Sanitary Surveillance Center – *CVS* and STD/AIDS Reference and Training Center – *CRT*), and linked to the Science, Technology and Health Strategic Supplies Coordination (incorporated by Blood, Components and Derivatives Group – *Hemorrede*), all of them linked to the São Paulo State Secretary of Health. The technical manual was written for establishing the criteria and rules on the use of plasma samples provided by blood bank and hemotherapy network[15]. At the initial phase of this task, a formal agreement was made between IAL and *Hemorrede* by means of a specific pact document[15], in order to IAL be responsible for conducting the technical activities in receiving, shipping, tracing assurance for plasma bags, and their exclusive usage for preparing materials for HIV ICQ.

In accordance with the mentioned agreement, there was an official approval to supply IAL with the HIV positive plasma bags and the plasma bags negative for serologic markers as ruled by *Resolução da Diretoria Colegiada* n. 153 of June 14th, 2004[16], or by that comes to replace it, for preparing the specific samples.

Preparation and technical skill building

Workshops, trainings, and meetings on ICQ establishment for HIV diagnostic routine testing were organized for providing information on general principles and consensus process to implement the analytical quality system at all laboratories of the São Paulo State Sub-Network, including the public laboratories and those private ones with a pact settled with the Brazilian Unique Health System (*SUS)*, which had previously applied to HIV AQCP[17,18]. In Brazil, the participation in the quality control program is not mandatory to any of laboratory units or institutions; nonetheless the participant laboratories were required to sign the agreement and responsibility form, and to send the official request for getting the specific serum panel. The respective technicians were also informed that before including the serum panel into routine test run, the IQC samples should be titrated in order to determine the suitable using dilution to get the optimal reactivity. In addition, the laboratories were instructed to report the assay kit in use, the lot number, the test manufacturer, the dilutions determined on the IQC samples, enclosing the recorded control chart on which the observed results were plotted. The reports on these data were made in a standardized form for further technical evaluation by IAL. Computer-assisted results assessment program (Microsoft Office Excel - Microsoft Corp., Redmont, WA,USA), set up at IAL, was employed for delineating the control chart with the results sent by those laboratories without plotting them in a control graph.

Preparation of serum panels

The supplied plasma bags were stored at -20º C until being processed; the plasma samples presenting lipemic or apparent turbidity aspects were discarded. In order to guarantee the samples tracking, all information on the received plasma bags were recorded in a proper registration book. The conversion of plasma into serum was carried out by means of thrombin technique[15,19] following the methodology recommended by WHO[19], with modification. After the frozen plasma being kept overnight at 2º–8ºC, the lyophilized human thrombin (1000 U/mL-Sigma, Steinheim, Germany), previously reconstituted with sterile deionized distilled water and stabilized for 120 min, was added into the plasma at a concentration of 1.25 IU/mL. After incubating overnight at 2º–8ºC, the supernatant (corresponding to serum sample) was recovered after centrifuging at 12,400xg (Beckman Instruments, Inc. Palo Alto, CA, USA) for 30 min at 4ºC. Then, 5-bromo-5-nitrol-1,3-dioxane – BCIP (bronidox L, Cognis. Jacareí, SP, Brazil) was added into the serum at a final concentration of 0.05%. Two serum aliquots were separated for performing the sample characterization and sterility test, respectively[20]. The serum panels were prepared following the specific Standard Operating Procedure (SOP) set out at HIV/AIDS Laboratory – IAL, and in accordance with the Good Manufacturing Practice for fractioning samples in aliquots, product packing and labeling procedures[21,22]. Before assembling the samples into the serum panels at IAL, the HIV Ab reactivity was certified by means of EIA/ELISA, Western blot technique and indirect immunofluorescence assay (HIV-1 IFA) on those samples previously characterized as HIV positive and on those sera negative for pertinent serologic markers[16]. HIV negative sera were characterized by HIV-1 IFA for selecting those specimens showing ideal negative staining, that is "red bricks" colour. For the sterility testing, one of the stored serum aliquots derived from each plasma bag was cultured onto chocolate agar, blood agar, BHI, Sabouraud agar, and agar-agar[20]. The serum samples were distributed into 2 mL-freezing vials, which were labeled and stored at -20ºC in cryogenic storage boxes.

Distribution of HIV IQC serum panels

After receiving the official request from the respective participant laboratories, the IAL delivered the serum panels, based on the following criteria (i) laboratory previously applied for HIV AQCP/SP; (ii) respective technician(s) who had previous technical training by attending workshops held in April and November, 2008; (iii) responsibility term previously settled and sent back to IAL[15,23]. The samples, either plasma or serum, were delivered in thermal boxes (Styrofoam cooler) containing dry ice, a thermometer to check the temperature maintenance at ≤ -20ºC, and the concerned document[15]. Each serum panel was set up accordingly to the day-to-day HIV serology routine testing carried out at respective

participant laboratory[15]. Thus, each laboratory received HIV IQC serum panel in a sufficient volume for being used for six to twelve months. Technical instruction manual and the forms to be filled in with obtained IQC results on every diagnostic test kit were sent with the panel.

HIV IQC serum panel use in the routine diagnostic testing runs

Before using the HIV IQC serum panel routinely, the participant laboratories calibrated the respective control sera to determine the appropriate dilution producing the optimal reactivity in HIV Ab testing kits as EIA/ELISA, microparticle enzyme immunoassay (MEIA), chemoluminescent (CMIA) and indirect immunofluorescence assay (IFA), routinely employed at each participant laboratory. For establishing the optimal reactivity of HIV-positive control serum to EIA/ELISA, MEIA, and/or CMIA, a 10-fold dilution of sample serially diluted from 1:10 to 1:100000 in negative serum was employed. Each serum dilution was tested in the respective HIV Ab assays kits available at respective laboratory. The best serum dilution to be employed as IQC sample corresponded to that showing an optimal optical density (OD) value at the range from 1.5 to 4.5 times the test cut-off (CO) rate. If more than one dilution of HIV positive IQC serum produced the ideal reactivity OD range, the dilution with the lowest OD value was chosen. However, if the optimal OD value was observed between two dilutions (e.g., between 1:1000 and 1:10000), the intermediate 2-fold dilutions were prepared from the most concentrated one (1:1000). Then, these serum dilutions were assayed in the same diagnostic test kit for finding that one presenting the optimal OD. In order to validate the prepared HIV IQC, 16 aliquots of this serum were set up on three runs (six aliquots at the first run, five at the second, and five at the third), recording the OD values and the respective CO. The OD/CO ratio values of 16 runs were calculated, and if they were within the acceptable variation range, the mean of sum total of OD/CO ratios was calculated and this was the base for drawing the quality control chart, plotting the finding data on the x-axis. From the fixed reference point (the mean value) on the chart, the superior and the inferior control limits for acceptable variations (±25%) were established, which were delineated on the graph. Each laboratory calculated its own mean value and control limits of each control sample in use. The data resulting from the HIV positive IQC serum were plotted on the control chart, and comparing with the previously established acceptable limits, the results dispersion was indicated around the mean value[13]. For validating the HIV IFA in the routine test run using the HIV IFA-IQC negative and positive (reactive at 1:16) sera, the expected reactivity pattern was remarked. The assay was rejected if any reactivity pattern variations on IQC sera occurred, not even the control sera from diagnostic test kit showed the expected reactivity. In this case, the potential reasons were investigated, and the respective correcting actions were applied before repeating the assay[13].

RESULTS

Production of serum panels for HIV IQC scheme

After establishing the pact[15] in October 2007, 43 plasma bags were supplied by the Beneficent Association for Blood Collection (COLSAN) of São Paulo to IAL, and the resulting seronegative samples were distributed into 3,787 aliquots (2.0mL/vial) and the HIV positive sera into 198 aliquots (2.0mL/vial), in accordance with the Technical Guide Manual[24]. The sterility testing of IQC sera demonstrated satisfactory results, which indicated the good quality of the prepared product.

Participant laboratories

A total of 109 professionals, from laboratories linked to São Paulo State Laboratory Sub-Network, were technically trained by IAL in April and November, 2008. Professionals from at least one laboratory of each Regional Health Department (*Departamento Regional de Saúde-DRS*) were trained. From May 2008 to February 2010, of 80 trained laboratories 44(55.0%) joined in the responsibility pact with the IAL-Central Lab; of 44 laboratories, 37(84.1%) requested the HIV IQC serum panels.

Application of HIV IQC scheme

From April 2009 to February 2010, the IAL provided the HIV IQC serum panels to 37 units of Laboratory Sub-Network. Twenty-seven (73.0%) out of 37 participant laboratories processed the HIV IQC serum panels following the recommended methodology of diagnostic test kits used in their routine work. They filled in the pertaining forms with obtained data in ELISA/EIA, MEIA and/or CMIA**,** and sent them back to HIV/

AIDS Laboratory of IAL. Of 27 participant laboratories, seven (25.9%) returned the complete information and the delineated quality control chart. Nine (33.3%) units did not draw the quality graph, but they sent all of the results from processing HIV IQC sera during day-to-day routine trials**.** Based on these data the respective control chart graphs were drawn by IAL-HIV/AIDS Laboratory staff. The other 11 (40.7%) units informed only the suitable dilution and the respective OD value of HIV positive IQC serum which was found in the used HIV Ab test kits; owing to the lack of these validation data, no control chart graph could be drawn by the IAL staff. Among those 37 participants laboratories, 22(59.5%) also perform HIV IFA in their routine testing, nevertheless 11 (50.0%) units only set up the IQC scheme for HIV IFA. Commercial HIV Ab assays of varied methodology and test formats employed by participant laboratories are shown in the Table. The optimal OD values for HIV IQC positive sera to ELISA/EIA, MEIA and for CMIA, and also the optimal dilution of HIV positive IQC sera in HIV-1 IFA are shown in the Table.

Assessing the HIV IQC scheme set up at participant laboratories

All participant laboratories received the respective serum panel containing the HIV positive samples that were processed from one plasma bag. The participant laboratories found either an identical optimal dilution for HIV IQC sera or a difference in one dilution, by using HIV diagnostic tests kits based on ELISA/EIA, MEIA and/or CMIA from the same manufacturers and from the same or different batch numbers (Table). Every quality control chart, drawn with results from the respective HIV IQC sera, was analyzed in accordance with the following parameters: (i) checking whether the IQC values were fallen within the acceptable limits, that is, whether the plotted measurement values were close to the fixed reference point – the mean value, indicating an adequate analytical performance and that the run was deemed valid as the measurements were not affected by variables; (ii) checking whether the daily IQC values were distant or spread in relation to the mean line, or they fell out of the acceptable variation interval; that is, whether the plotted values exceeded ±25% of arithmetic mean**.** These systematic errors were informed to the technicians of respective laboratory for correcting them which might be induced by some factors. In analyzing those l6 HIV positive IQC control chart curves (seven delineated by the respective laboratories and nine graphs plotted by IAL staff based on the informed OD/CO ratios data from daily runs), two of the last nine control graphs indicated the ideal values for HIV IQC serum within acceptable variation range, but the plotted results were in a spreading pattern, being alternately close to the superior and inferior limits as shifts or trends away from the mean value. The IAL staff kept in contact with those two laboratories to help them in improving the serologic testing practice and procedures, and to take corrective measures.

During the HIV IQC setting up in the routine testing of participant laboratories, they were individually monitored by the IAL-HIV/AIDS Laboratory staff, and the technical support was provided on how to develop and to operate the IQC methodology. Also the contact was maintained with the technicians to advise them in carrying out every step of the pertaining procedures.

DISCUSSION

Numerous variables may affect the quality of final results, which may be caused by diverse errors at every step of HIV serologic testing, such as: biological samples erroneously identified or mislabeling, contaminated samples, clinical specimens data input error, test reagents mishandling, alteration in testing technique, inadequately calibrated equipments, misinterpretation of test results, result transcription errors, and unsatisfactory supervision[24]. Laboratory performance improves after introducing the IQC scheme into routine testing run**.** This system is helpful in identifying the majority of variables that affect the quality of final results, although some random errors are difficult to be elucidated and eliminated[24, 25].

The use of the IQC scheme during the analytical phase of every serologic assay run provides additional parameters for validating the test and to identify the variations in the every batch of diagnostic reagents kits in use. These measures produce good quality laboratory outcomes by monitoring both random and systematic errors, which could not be detected when only those kit control sera provided by the manufacturer are employed[26-28].

Random errors are difficult to be eliminated, though they can be minimized by training and technical supervision**;** the repetition also reduces the effects of random errors. The errors occur in an unpredictable manner, yet by introducing IQC into diagnostic routine work they might be significantly reduced.

Table. Optimal dilution for HIV IQC sera panel samples on anti-HIV antibody ELISA/EIA, MEIA and IFA tests kits determined by participant laboratories

Laboratories	Diagnostic test kits	Lot number	Serum dilution
1	Axsym HIV 1/2 gO – Abbott	71346LF00	1:.8000
	Vironostika HIV Uni-Form Plus O - Biomérieux	A49MA	1:10000
	IFA – HIV-1 - BioManguinhos	080VH027Z	1:32
2	Axsym HIV 1/2 gO - Abbott	74406LF00	1:10000
3	Axsym HIV 1/2 gO - Abbott	73274LF00	1:10000
	Murex HIV 1.2.O - Abbott	L159110	1:80000
	IFA – HIV-1 - BioManguinhos	093VH003Z	1:32
4	Anti-HIV Tetra ELISA – Diasorin	3829051	1:2 000
	Vironostika HIV Uni-form Plus O – Biomérieux	A49HC	1:10000
	IFA – HIV-1 - BioManguinhos	097VH010Z	1:8
5	Vironostika HIV Uni-form Plus O - Biomérieux	A49MA	1:10000
6	Anti-HIV 1/2 Dade – Behring	38595	1:1000
7	Anti- HIV 1/2 SYM - Symbiosis	1000100210	1:1000
	Geenscreen Ultra HIV Ag-Ab - Bio-Rad	8K0572	1:10000
	IFA – HIV-1 - BioManguinhos	093VH002Z	1:16
8	Axsym HIV 1/2 gO - Abbott	74406LF00	1:10000
9	Axsym HIV 1/2 gO - Abbott	76367LF01	1:10000
	Vironostika HIV Uni-form Plus O Biomérieux	A49LA	1:10000
10	Anti-HIV Tetra ELISA - Diasorin	3819071	1:1000
	Vironostika HIV Uni-form Plus O Biomérieux	040AB	1:10000
	IFA – HIV-1 - BioManguinhos	096VH009Z	1:8
11	Anti- HIV 1/2 SYM - Symbiosis	1000000370	1:1000
	Detect HIV 1/2 (V.4) - Adaltis	11089	1:10000
12	Axsym HIV 1/2 gO – Abbott	76367LF01	1:10000
	Anti-HIV Tetra ELISA – Diasorin	3839071	1:1000
	Vironostika HIV Uni-form Plus O - Biomérieux	049MA	1:10000
	IFA – HIV-1 - BioManguinhos	099VH016Z	1:16
13	Anti-HIV Tetra ELISA - Diasorin	3827041	1:1000
	IFA – HIV-1 - BioManguinhos	090VH018Z	1:8
14	Anti-HIV Tetra ELISA - Diasorin	3839071	1:1000
	Vironostika HIV Uni-form Plus O - Biomérieux	A49MA	1:10000
	IFA – HIV-1 - BioManguinhos	096VH009Z	1:32
15	Axsym HIV 1/2 gO – Abbott	73448lf02	1:10000
	Vironostika HIV Uni-form Plus O - Biomérieux	A49MA	1:10000
16	Axsym HIV 1/2 gO – Abbott	76376LF00	1:8000
	Murex HIV 1.2.O - Abbott	L252110	1:40000
	IFA – HIV-1 - BioManguinhos	096VH008Z	1:16
17	Vironostika HIV Uni-form Plus O – Biomérieux	A40AB	1:8000
	IFA – HIV-1 - BioManguinhos	098VH012Z	1:8
18	Axsym HIV 1/2 gO – Abbott	76367LF01	1:8000
	Anti-HIV Tetra ELISA - Diasorin	3527041	1:1000
	Vironostika HIV Uni-form Plus O - Biomérieux	040AB	1:10000
19	Axsym HIV 1/2 gO – Abbott	76367LF01	1:10000
	Anti-HIV Tetra ELISA - Diasorin	3827041	1:2000
	Vironostika HIV Uni-form Plus O - Biomérieux	040AB	1:10000
20	Architect HIV Ag/Ab Combo – Abbott	76452HN00	1:8000
	IFA – HIV-1 - BioManguinhos	093VH027Z	1:4
21	Vironostika HIV Uni-form Plus O – Biomérieux	A49MC	1:10000
22	Vironostika HIV Uni-form Plus O – Biomérieux	A40AB	1:10000
23	Architect HIV Ag/Ab Combo – Abbott	75843HN00	1:10000
24	HIV Combi - Roche	154645	1:40000
25	Axsym HIV 1/2 gO – Abbott	81241LF00	1:10000
	Vironostika HIV Uni-form Plus O - Biomérieux	A40FB	1:10000
26	Axsym HIV 1/2 gO – Abbott	81241 LF 00	1:10000
27	Architect HIV Ag/Ab Combo – Abbott	75843HN00	1:8000
	Vironostika HIV Uni-form Plus O - Biomérieux	A40AB	1:8000

Laboratory test reliability is one of the most concerning components within the scope of medical care, moreover the procedures for monitoring analytical performance and the good quality of diagnostic testing are the essential requisites for any clinical laboratory for achieving reliable final results. In fact, the use of HIV IQC in the daily diagnostic routine work helps laboratories to be on the alert to scrutinize and to review every step of performed procedures for correcting the identified errors, for improving the daily work and for continuing improvement of diagnostic processes.

In view of the identical optimal dilutions of positive IQC sample found by the participant laboratories on diverse HIV Ab kits from the same manufacturers and from different batches, it might be inferred that the laboratories adequately followed the procedure described in the Technical Guideline Manual[15], also in correctly carrying out the HIV Ab testing in accordance to the manufacturers' recommendations. The HIV Ab test kits mostly available at the participant laboratories (Table) seemed to be of good quality and of significant reproducibility. Regarding to HIV IQC-IFA positive serum, whose titer was 16, among 11 laboratories one laboratory only reported as positive at dilution 1:4, indicating that it could not manage to get the adequate reactivity equal to 1:16 or ± one dilution (Table). The IAL staff advised this laboratory to make arrangements to ask for a technical assistance for the fluorescence microscopy in use at that laboratory.

The technology applied by IAL-Central Lab for producing the HIV IQC serum panels is a low-cost process and no complex equipment is required. Introduction of an internal quality control scheme is needed for assuring that valid results obtained from IQC sera continue to be effective. It implies that systematically use of internal control samples, both at every test run and on each batch of diagnostic test kits, ought to evidence the reproducibility of final results, and that the methodology presents accuracy in detecting the specific analyte on each sample in analysis. When the test is in control, these acceptable limits define the range in which the results are expected to fall. In this context, the individual control graph drawing at each laboratory for monitoring the accuracy of test results enables to identify and to correct the systematic and random variables.

The present work developed at the HIV/AIDS Laboratory of IAL-Central Laboratory has contributed to strengthening the institutional role. The activities in progress provide the technology development, which improve the technical skill of participant professionals, and consequently the quality of HIV/AIDS serologic testing. With the purpose of establishing proceedings on serologic assays, quality improvement, inter-assay standardization of commercial immunoassay kits, the laboratories of the São Paulo State HIV Ab testing Sub-Network have been motivated to join the HIV/SP AQCP in order to introduce the HIV IQC scheme into the respective laboratory routine work. Therefore, several units that perform HIV Ab testing and take part in the São Paulo State Laboratory Sub-Network have already applied to HIV AQCP. And to those units which have not done the application yet, they have been asked to apply to the respective program by assessing the site www.ial.sp.gov.br.

Stability studies are in progress to ensure that the properties of samples components of HIV IQC serum panels are long-standing. The samples stability test is assayed from the sera aliquot preparation step to the anticipated expiration date.

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