J Bras Patol Med Lab, v. 53, n. 3, p. 194-195, June 2017

10.5935/1676-2444.20170030

Creation of a comprehensive proficiency testing program for molecular diagnosis in Brazil

Criação de um amplo programa de ensaios de proficiência para o diagnóstico molecular no Brasil

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Key words: laboratory proficiency testing; molecular pathology.

TO THE EDITOR

External quality assessment (EQA) consists in the comparison of results from a laboratory with those from an external source – a group of laboratories or a reference laboratory. The implementation of a program of this nature helps the laboratory ensure reliable results; besides, it is required by law and accreditation organizations[1].

Proficiency testing is one of the forms to carry out EQA. In this case, an external provider sends "blind" samples to a group of laboratories; the results reported by participants are compared and analyzed by the provider, which produces a performance report. Based on performance, participants can evaluate the reliability of their methods, materials, equipment, and training. In case a problem is identified, corrective actions can be taken[2].

In the absence of proficiency testing, EQA is done in an alternative manner: interlaboratory comparison, clinical validation, or analysis of reference samples[3]. So far, in Brazil, alternative EQA is the only option for most analytes in molecular diagnosis, such as cytomegalovirus, *Chlamydia trachomatis* and *Neisseria gonorrhoeae*.

In practice, organizing an alternative EQA is not trivial[4]. Issues that must be solved include frequency of comparisons, number of samples, stability and transport, lack of a reference laboratory, definition of assessment criteria, reduced number of laboratories participating in the comparison, delay for the procedure to be completed, and price[5].

In 2016, during the emergence of Zika virus epidemic in Brazil[6], some laboratories began to offer molecular testing for its detection. At the same time, proficiency testing was organized by Controllab, a provider accredited according to the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17043, with experience of more than 40 years in the development and the conduction of proficiency testing programs. After conduction of the first proficiency testing round, Laboratório Sabin characterized samples and also provided materials with known results to Controllab. That joint effort resulted in a proficiency testing with quarterly evaluations which, nowadays, counts on the participation of 14 laboratories, contributing to the quality of Zika virus detection in our territory.

Due to that successful experience, both companies decided to extend partnership concerning other analytes for molecular diagnosis, including infectious diseases and genetic tests.

Controllab already makes quality control available for dengue fever, chikungunya, genetic profiling (paternity and maternity tests) and serological markers. In partnership with Laboratório Sabin, the following assays will be included: cytomegalovirus; *Chlamydia trachomatis*; *Neisseria gonorrhoeae*; human papillomavirus; factor V Leiden; 20210A variant in the prothrombin gene (FII); 282Y and 63D variants in the hemochromatosis gene (HFE); 677T variant in the methylene tetrahydrofolate reductase gene (MTHFR); -13910T variant in the lactase gene (LCT) promoter; V617F variant in the Janus kinase 2 gene (JAK2); allele B27 of the gene of the major histocompatibility complex class I (HLA-B27); E2, E3

First submission on 29/03/17; last submission on 29/03/17; accepted for publication on 18/04/17; published on 20/06/17

and E4 variants of apolipoprotein E (APOE) gene; prenatal sex determination; e13/a2 and e14/a2 fusion transcripts between breakpoint cluster region (BCR) gene and Abelson murine leukemia viral oncogene homolog 1 (ABL1); and others.

Therefore, a comprehensive proficiency program is born for molecular diagnosis in Brazil, which will be able to improve uniformity of results among laboratories, as well as assure quality and safety for thousands of patients.

Unitermos: *ensaio de proficiência laboratorial; patologia molecular.*

REFERENCES

1. Miller WG, Jones GR, Horowitz GL, Weykamp C. Proficiency testing/external quality assessment: current challenges and future directions. Clin Chem. 2011; 57: 1670-80.

2. Miller WG. The role of proficiency testing in achieving standardization and harmonization between laboratories. Clin Biochem. 2009; 42: 232-5.

3. Kalman LV, Lubin IM, Barker S, et al. Current landscape and new paradigms of proficiency testing and external quality assessment for molecular genetics. Arch Pathol Lab Med. 2013; 137: 983-8.

4. Richards CS, Grody WW. Alternative approaches to proficiency testing in molecular genetics. Clin Chem. 2003; 49: 717-8.

5. Albuquerque C, Mendes ME. Gestão da fase analítica do laboratório: como assegurar a qualidade na prática. Controllab. 2011; 2: 82-5.

6. Bogoch II, Brady OJ, Kraemer MU, et al. Anticipating the international spread of Zika virus from Brazil. Lancet. 2016; 387: 335-6.

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