THE INTERNATIONAL QUALITY STANDARDS FOR PT PROVIDER AND KBUDEK (TURKISH E.Q.C. EXPERIENCE)

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Abstract

PT programmes are the main instruments that provide data to improve analytic performance of participant laboratories. (ISO / IEC 43 1997, ISO 13528 2006 , ILAC G 13 2000). Beside that it provides
1) Interlaboratory comparison of analytical performance
2) Comparison of metod dependent analytical performance
3) Control of diagnostic tests
4) Education of laboratory staff
PT programmes are the main tool of quality management system of clinical laboratories. PT providers should at least ensure base quality standarts which are recomended by ILAC G-13 document. In this standart;
1- Management requirements and KBUDEK
A- Management and organizational chart of kbudek is proper for recommended standarts
B- Quality management system of KBUDEK is proper for the recommended standarts of this document. Statistycal design was established according to ISO 13528 document.
C- Each of the reports that are send to the participant laboratories for performance assesment is proper to ILAC G 13 2000 2.3.
2- Technical requirements and KBUDEK
A- The samples that are sent to the participant laboratories to measure, are all CRM that their homogenity and stability are tested before sending to participants.
B- The method of assessment of data and analysis of performance are designed for the ISO 13528 2006 standards.

C- The transportation of reference material, the designation of inserts and end product evaluating for reference material are proper for ILAC G-13 2000 / 3.5.2.

D- The confidentiality of each reports belongs to the participant laboratories are ensured by the technical manager and quality control consultant of KBUDEK as it is recommended by ILAC G-13 2000 3.8.

AFTER ALL THESE EXPLANATIONS IT IS CLEARLY SEEN THAT TURKEY HAS A NATIONAL EXTERNAL QUALITY CONTROL PROGRAMME FOR CLINICAL LABORATORIES WHICH IS READY TO BE ACREDITED.

Key words

External quality control

External quality control or proficiency testing programmes are the main instruments that provide data to improve analytic performance to the participant laboratories (ISO 13528: 2006, ILAC G 13: 2000). Beside that it provides 1) Interlaboratory comparison of analytical performance of the laboratory, 2) Comparison of method dependent analytical performance, 3) Control of diagnostic tests, 4) Education of laboratory staff. External quality control programmes are the main tool for quality management. External quality control testing providers should at least ensure base quality standards which are recommended by ILAC in the ILAC G-13 document. According to this document: 1-Management requirements and KBUDEK a) Management and organizational chart of k渡ek abide for recommended standards by this document (ILAC G-13); b) Quality management system of KBUDEK follows the recommended standards of this document. Statistical design was established according to ISO 13528 document. Operational procedure and content of participant laboratory reports are proper for ILAC G-13: 2000 which is the last determined standard for PT providers by ISO. Confidentiality and ethical procedure are designed for this document; c) Each of the reports that are send to the participant laboratories for performance assessment is preferred according to ILAC G 13:2000 2.3. All the contracts which have been performed with the subcontractor firms are proper to ILAC G 13: 2000 2.5.

2-Technical requirements and KBUDEK

a) The samples that are sent to the participant laboratories to measure, are all Certified Reference Material that their homogeneity and stability are tested before sending to participants .KBUDEK buy these samples from a firm that ensure the recommended quality performance about the quality control samples

b) The method of assessment of data and analysis of performance that belongs participants laboratory are designed as described by the ISO 13528 2006 standards,

c) The transportation of reference material to the laboratories, the designation of insert sheaths of them and end product evaluation for reference material are as described in ILAC G-13 2000 / 3.5.2.

d) The confidentiality of each report belonging to the participant laboratories are ensured by the technical manager and quality control consultant of KBUDEK as it is recommended by ILAC G-13 2000 3.8.
KBUDEK is unique national external quality control programme in Turkey; proper and ready for accreditation processes according to ILAC G-13 and other international standard documents.

1 EXTERNAL QUALİTY CONTROL
External quality control or proficiency testing programmes are the main instruments that provide data to improve analytic performance to the participant laboratories. (ISO 13528 2006, ILAC G 13 2000). Beside that it provides
1) Interlaboratory comparison of analytical performance of the laboratory,
2) Comparison of method dependent analytical performance,
3) Control of diagnostic tests,
4) Education of laboratory staff.

External quality control programmes are the main tool for quality management.

Figure 1: QUALITY ASSUREANCE SYSTEM MEMBERS

2 KBUDEK AND QUALİTY CONTROL PROGRAMMES REQUIREMENTS

External quality control testing providers should at least ensure base quality standards which are recommended by ILAC in the ILAC G-13 document. According to this document.
1) Management requirements and KBUDEK
   a) Management and organizational chart of kbuşek abide for recommended standarts by this document
   b) Quality management system of KBUDEK follows the recommended standarts of this document.
Figure 2: STEP BY STEP EXTERNAL QUALITY CONTROL ASSESSMENT

Figure 3: KBUDEK ORGANIZATIONAL CHART

1-Management requirements and KBUDEK

a) Management and organizational chart of KBUDEK abide by recommended standards by this document (ILAC G-13)

b) Quality management system of KBUDEK follows the recommended standards of this document. Statistical design was established according to ISO 13528 document. Operational procedure and content of participant laboratory reports are proper for ILAC G-13 2000 which is the last determined standard for PT providers by ISO. Confidentiality and ethical procedure are designed for this document.
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REFERENCES

