تقديم

الهيئة العامة للغذاء والدواء جهة مستقلة الغرض الأساسي لها هو القيام بتنظيم ومراقبة الغذاء والدواء والأجهزة والمنتجات الطبية والتشخيصية، ومن مهامها وضع اللوائح الفنية والمواصفات في مجالات الغذاء والدواء والأجهزة والمنتجات الطبية سواءً كانت مستوردة أو مصنعة محلياً بواسطة لجان فنية متخصصة، وقد قام قطاع الأجهزة والمنتجات الطبية بالهيئة ضمن برنامج عمل الفريق رقم (SFDA/MDS/TC 212) "فريق عمل مواصفات الفحوصات المخبرية السريرية وأجهزة الاختبار التشخيصي" بتبني المواصفة الدولية رقم (ISO 18153:2003) "الأجهزة الطبية المخبرية التشخيصية -- القياس الكمي للعينات الحيوية -- سلسلة القياس (التتبع) لقيم تركيز محفزات الانزيمات في مواد المعايرة و المراقبة"، والتي أصدرتها "المنظمة الدولية للتقييس" وذلك بلغتها الأصلية. وقد اعتمدت هذه المواصفة كمواصفة سعودية متبناة بالمطابقة بلغتها الأصلية وذلك في اجتماع مجلس الإدارة رقم ( ) والذي عقد بتاريخ (../../١٤.. هـ) الموافق (../../٢٠.. م).

Foreword

Saudi Food and Drug Authority (SFDA) is an independent organization with main purpose of regulating and monitoring of foods, drugs and medical devices. One of SFDA functions is to issue national Standards /Technical Regulation in the fields of foods, drugs and medical devices, whether imported or manufactured locally, through specialized technical committees (TCs).SFDA medical devices sector through the work program of technical committee (SFDA/MDS/TC 212) “Clinical laboratory testing and in vitro diagnostic test systems” has adopted the International Standard No. (ISO 18153:2003) " In vitro diagnostic medical devices -- Measurement of quantities in biological samples -- Metrological traceability of values for catalytic concentration of enzymes assigned calibrators and control materials” issued by “International Organization for Standardization” in its original language. This standard is identically adopted in its original language and has been approved as national standard by SFDA board of directors in its meeting No ( ) Held on (../../14..AH), agreed with (../../20..G).

Scope

This European Standard specifies how to assure the metrological traceability of values assigned to calibrators and control materials intended to establish or verify trueness of measurement of the catalytic concentration of enzymes.

The calibrators and control materials are those provided by the manufacturers as part of, or to be used together with, in vitro diagnostic medical devices.

The following subjects are outside the scope of this standard:

a) requirements for the design or selection of a reference measurement procedure;

b) quantities involving mass of enzyme or immunoreactivity of enzymes;

c) control materials that do not have an assigned value and are used only for assessing the precision of a measurement procedure, either its repeatability or reproducibility (precision control materials);

d) control materials intended for intralaboratory quality control purposes and supplied with intervals of suggested acceptable values, each interval obtained by interlaboratory consensus with respect to one specified measurement procedure, and with limiting values that are not metrologically traceable;

e) metrological traceability of routine results to the product calibrator and their relations to any medical discrimination limit;

f) properties involving nominal and ordinal scales.