BS ISO 21474-3:2024

BSI Standards Publication

In vitro diagnostic medical devices — Multiplex molecular testing for nucleic acids

Part 3: Interpretation and reports

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A list of organizations represented on this committee can be obtained on request to its committee manager.

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Part 3: Interpretation and reports

Dispositifs médicaux de diagnostic in vitro — Tests moléculaires multiplex pour les acides nucléiques —

Partie 3: Interprétation et rapports

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Foreword

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Introduction

The first generation of in vitro diagnostic (IVD) medical devices for nucleic acid-based molecular tests has been focused on detection or quantitation of a single nucleic acid sequence (e.g. viral RNA, mRNA, or genomic DNA) within a clinical specimen. By comparison, a multiplex molecular test simultaneously measures multiple nucleic acid sequences of interest in a single reaction tube or a system. The development and clinical use of multiplex IVD medical devices are rapidly expanding with the technological advances and new elucidation of the clinical significance of many biomarkers.

In comparison to single target analysis, multiplex molecular tests require an increased number of controls, more complex performance evaluation/data analysis algorithms, and more complex interpretation and reporting of results.[1,2] Some multiplex systems amplify multiple targets in a single reaction step and then split these into reactions for specific target detection.[3]

Laboratories can develop assays in-house ("laboratory-developed test (LDT)", "home-brew", or "in-house test") or use commercially available multiplex assays involving a variety of technologies and instrument platforms. Multiplex molecular testing provides large amounts of complicated and multifarious genetic information, resulting in significant challenges to the laboratory with regards to appropriate data analysis, interpretation and reporting.

Implementation of a multiplex molecular test identifies large numbers of genetic variations in a sample, which is crucial for optimal patient care, and treatment guidelines are developed based on specific molecular findings; therefore, it is imperative to standardize the interpretation and reporting of molecular results among laboratories performing these tests.

This document describes the requirements and recommendations for various aspects of interpretation and reporting of the results by multiplex molecular tests in order to ensure the quality of laboratory services of such tests, in implementing multiplex molecular nucleic acid tests for clinical use.

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