

Management and use of IVD point of care test devices

Medical Devices Agency - Requirements for point of care testing systems



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Point

On , based on FDA's continued review of the scientific evidence available for Chembio Diagnostic Systems, Inc.

POCTED: Use of Point of Care Test Devices in Emergency Department

Even today, IVD testing is concentrated in large laboratories affiliated with 2,418 top-tier aka class III hospitals in the major cities. This new approach provides rapid, highly sensitive and low-cost testing, in addition to improving diagnostic, therapeutic, and monitoring practices, thus, increasing patient satisfaction. The problem of managing these devices gets compounded with multiple vendor devices with proprietary interfaces.

Point of Care Testing (POCT)

Food and Drug Administration has 120 tests for use by non-laboratory trained personnel, Hattingh says.

Regulating the Point of Care: The IVD Connectivity Industry Consortium

It provides with rapid results that are useful in making clinical decision by the doctor making it convenient for patients and care providers as well. An awareness of the expected rate of false positive and false negative results will be required to inform this practice.

The role of POCT and rapid testing

The Careside Analyzer offers a broad menu of routine blood tests, currently including 37 FDA-cleared or FDA-exempt tests or test parameters in the three categories of chemistry, electrochemistry, and coagulation. It will be possible to identify many test combinations for inclusion in novel POCT technologies, as more clinical diagnostic and therapeutic data is collected and analyzed through connected devices. To ensure reliability of these devices at the point of care, it is important to manage these devices for quality of results.

POCTED: Use of Point of Care Test Devices in Emergency Department

Providing results in different units, for example, could cause confusion.

In Vitro Diagnostics Medical Devices Regulation (IVDR)

POCT1-A2 addresses the problems of Point of Care Testing device connectivity and message formats for information exchange between POC data manager and the device for patient results, operator list, patient list, calibration and QC results, and other scenarios. That would make compliance challenging for retail pharmacies that operate nationwide.

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