

Computer Based Diagnosis for Haematology Patient

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ABOUT THE STUDY

Haematology analysers that can perform a Complete Blood Count (CBC) have a long way to go in terms of adoption at the point of care. Sight OLO is an innovative haematological stage that gives a 19 parameter, five section differential CBC and is intended to address the obstacle of current point of care haematology analysers by fusing current advances in Artificial Intelligence (AI) and computer vision. The OLO system was compared to the Sysmex XN Series System in terms of accuracy, repeatability, and flagging capabilities (Sysmex, Japan). The performance of venous, capillary and fingerpick blood samples was examined in matrix studies. Regression study reveals a high level of agreement between OLO and the Sysmex XN, indicating that OLO is very accurate for all CBC parameters. The majority of the testing parameters showed high repeatability and reproducibility. In a multicentre clinical laboratory setting, the OLO haematology analyser's analytical performance was validated, proving its accuracy and comparability to clinical laboratory-based haematology analysers.

Sight OLO is a desktop haematology platform built from the ground up for point of care and near patient applications. Single use test kits are used in the device, which utilizes a novel approach for generating and colouring blood smears within disposable test cartridges (see "sample preparation" below). OLO's automated fluorescence microscope quickly images these monolayer blood smears, yielding a series of over 1000 multispectral micrographs per sample. The images are evaluated on board using OLO's on board computer using a series of specifically created algorithms, resulting in the 19 stated CBC values and various flags, including the presence of nucleated RBCs, blast cells, immature granulocytes, and unusual lymphocytes in WBC. The diagnostic result is then shown on OLO's touchscreen interface, a paper printout is optionally provided, and the result is digitally transmitted to a Laboratory

Information Management System (LIMS) or an Electronic Medical Records (EMR) system.

The device is 32 cm × 28 cm × 25 cm (about one cubic foot) and contains no reagents instead, reagents are kept within each test kit, eliminating the need for regular instrument washouts. Sight OLO is factory calibrated, thus it doesn't need to be calibrated regularly. By ensuring that all optical, mechanical, and electronic elements of the system that may have a direct effect on the analyser calibration (for example, LED intensities, illumination maps, focus mechanism, cartridge levelling, and so on) remain within allowed ranges and are enforced by a lock-out method, the analyser calibration can be maintained. The failsafe system from Sight OLO acts as internal quality control to verify that the device is operating properly, obviating the need for external Quality Control (QC) materials unless required by law. Furthermore, the failsafe system is designed to prevent human errors, consumable flaws, and blood sample anomalies by rejecting such samples so that the analyser does not produce incorrect results.

CONCLUSION

The performance of the Sight OLO haematological analyser was effectively validated in a multicentre clinical laboratory setting in the study described here. The study found that OLO is as accurate as an equivalent to the well known Sysmex XN Series Haematology Analysers. This study led to OLO's FDA 510(k) clearance and demonstrates the capabilities of multi-spectral live monolayer imaging and AI-assisted image analysis in haematology. Sight OLO was able to yield findings from fingerpicks that were equivalent to those acquired from venous blood draws, demonstrating the validity of performing five-part differential CBC analysis utilizing direct-from-finger blood samples. The FDA has certified OLO to collect samples directly from fingerpicks, making it the first CBC analyser to do so.

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