

IMMUNOHEMATOLOGY

Remote Result Management Software

IH-Web

This statement is intended to provide a summary of the IT environment and security considerations concerning **IH-Web Remote Result Management Software**.



What is **IH-Web**?

IH-Web is an additional software module for **IH-Com** which enables requests and results to be remotely managed via the internet protocol using a standard web browser.

What is **IH-Com**?

IH-Com is a software package intended to be used as an interface between automated blood banking instruments and the Blood Establishment Computer Software. **IH-Com** is for use by trained laboratory personnel, in a blood banking environment, to assist with result interpretation, data management and instrument control.

What are the Functions of **IH-Web**?

With **IH-Web**, users have the possibility to remotely access the **IH-Com** database, manage requests, search previous records, add supplementary tests and validate results from any location and at any time.

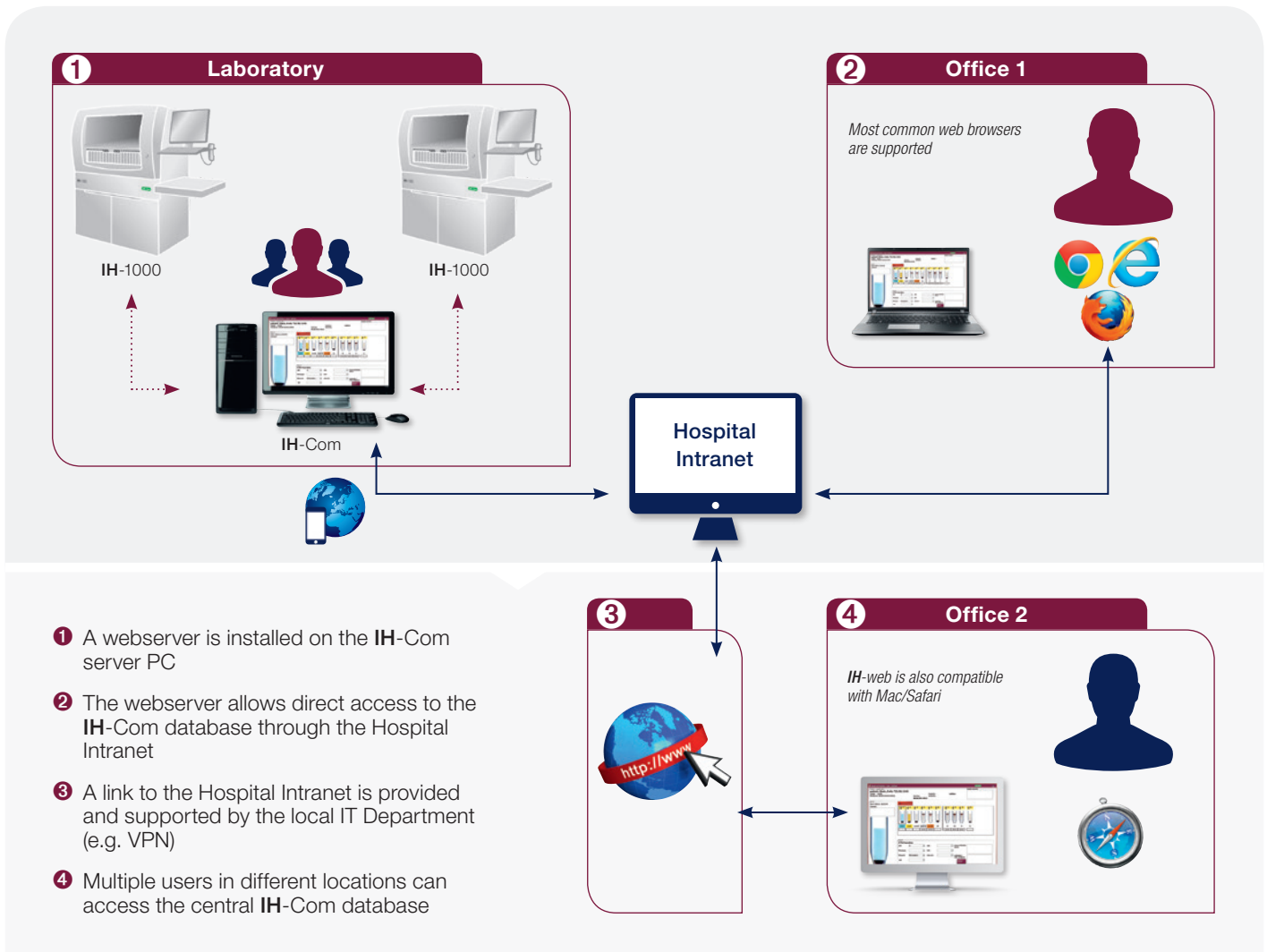
How is **IH-Web** Configured?

A web server is required to access the **IH-Com** database. **IH-Web** uses Internet Information Services from Microsoft as the default web server. During installation of **IH-Web**, the web server is configured for remote access to **IH-Com** and firewall rules are automatically defined.

IH-Web uses the Internet Protocol (TCP/IP). It never should be used without encryption over the internet. Operation is acceptable only within an intranet. Encrypted connections are possible by SSL (<https://>) or VPN.



Network Configuration of IH-Web



What are the Cyber Security Considerations for the use of IH-Web?

IH-Web operates via a web browser client/server system. No additional risks in terms of unauthorized access, modification or misuse have been identified. Any possible risk is inherent to the network through which IH-Web is accessed. All network security measures already in place are applicable also to IH-Web during routine operation.

The cyber security considerations on operation with IH-Web were made on the basis of the recommendations as described in "Content of Pre-market Submissions for Management of cyber security in Medical Devices - Guidance for Industry and Food and Drug Administration Staff, October 2, 2014".

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