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SHORT COMMUNICATION

Multicenter Performance Evaluation of Elecsys Anti-HBc II, Anti-HCV II, HIV combi PT, HBsAg II, and Syphilis Immunoassays

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SUMMARY

Background: **The WHO recommends mandatory serological testing of blood donors for hepatitis B virus, hepatitis C virus (HCV), human immunodeficiency virus (HIV), and syphilis. We evaluated the performance of Elecsys® infectious disease immunoassays against commercially available comparator assays.**
Methods: **Prospective, routine, anonymized patient or donor samples (n = 8,821) were analyzed at three German sites using Elecsys anti-hepatitis B core antigen (Anti-HBc II), Anti-HCV II, HIV combi PT, hepatitis B surface antigen (HBsAg II), and Syphilis immunoassays (cobas e 411 analyzer) versus ARCHITECT comparator assays.**
Results: **The Elecsys immunoassays demonstrated comparable sensitivity (≤ 1.54% difference) and equivalent specificity (≤ 0.63% difference) to the respective ARCHITECT comparator assays. Overall sensitivity for the Elecsys and ARCHITECT infectious disease panels was 99.78% vs. 99.40%, respectively, and overall specificity was 99.74% vs. 99.80%, respectively.**
Conclusions: **The Elecsys infectious disease immunoassays demonstrated high sensitivity and specificity, which were similar to comparator assays, supporting their suitability for routine laboratory practice.**
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Supplementary Tables and Figures

Appendix A. Supplementary Data
Supplementary Methods

Study design - sample storage conditions
All assays, with the exception of the syphilis assays at the Regensburg site, were evaluated in parallel to routine testing, and samples were stored according to individual institution guidelines. Syphilis assay evaluations were performed at Regensburg using samples stored at -20°C. At MVZ Labor Krone GbR, Bad Salzuflen, the samples were tested in parallel to routine testing within 3 days of sample arrival; samples were stored at 4°C.

Elecsys infectious disease immunoassays and confirmatory methods
Elecsys® anti-hepatitis B core antigen (Anti-HBc II) is a two-step, competitive immunoassay able to detect total immunoglobulin G and M against HBc in 27 minutes (cutoff index [COI] values: > 1.0 non-reactive; ≤ 1.0 reactive) [1]. Elecsys anti-hepatitis C virus (Anti-HCV II) is a one-step, double-antigen sandwich immunoassay for the determination of antibodies against HCV (COI values: < 0.9 non-reactive; 0.9 - < 1.0 borderline; ≥ 1.0 reactive) with a run time of 18 minutes [2]. Elecsys human immunodeficiency virus (HIV) combi PT is a two-step, double antibody/antigen sandwich immunoassay for the detection of HIV-1 p24 antigen and antibodies to HIV-1 (including group 0) and HIV-2, with the result determined within 27 minutes (COI values: < 0.9 non-reactive; 0.9 - < 1.0 borderline; ≥ 1.0 reactive) [3]. Elecsys hepatitis B surface antigen (HBsAg II) is a one-step, double-antigen sandwich immunoassay designed to detect HBsAg with a test time of 18 minutes (COI values: < 0.9 non-reactive; 0.9 - < 1.0 borderline; ≥ 1.0 reactive) [4]. Elecsys Syphilis is a one-step, double-antigen sandwich immunoassay for the determination of total antibodies against *Treponema pallidum* antigens TpN15, TpN17 and TpN47 (COI values: < 1.0 non-reactive; ≥ 1.0 reactive) [5].
Confirmatory methods were carried out for discrepancies between the Elecsys and the corresponding ARCHITECT assays, borderline results, and repeatedly positive results in order to determine true positives. All confirmatory methods were performed at the respective sites that performed the initial tests (Table S1). For each assay, the methods were as follows:

- Anti-HBc: confirmatory tests were performed with a third assay, in order to determine the majority result. HBV-DNA nucleic acid testing (NAT) was used to further characterize active infection.
- Anti-HCV: anti-HCV confirmatory assay, HCV immunoblot, and HCV-RNA NAT (to characterize active infection).
- HIV: HIV immunoblot, Elecsys HIV Ag confirmatory test, and HIV-RNA NAT (to characterize active infection).
- HBsAg: HBsAg confirmatory assay and HBV-DNA NAT (to characterize active infection).
- Syphilis: quantitative syphilis assay and syphilis immunoblot at the Regensburg site. For samples at MVZ Labor Krone GbR, in the case of a positive or borderline screening result, TPPA (Fujirebio Inc., Tokyo, Japan) and IgG-FTA-Abs tests were used as confirmatory tests. In the case of discrepant results, venereal disease research laboratory testing (Treponema + VDRL ViraBlot Test-kit IgG, IgM [Viramed Biotech AG, Planegg, Germany]) was implemented.

References:

1. Elecsys Anti-HBc II assay [package insert]. Roche Diagnostics GmbH; Mannheim, Germany; 2018 (revised May 2019).
2. Elecsys Anti-HCV II assay [package insert]. Roche Diagnostics GmbH; Mannheim, Germany; 2018 (revised September 2019).
3. Elecsys HIV combi PT assay [package insert]. Roche Diagnostics GmbH; Mannheim, Germany; 2019 (revised July 2019).
4. Elecsys HBsAg II assay [package insert]. Roche Diagnostics GmbH; Mannheim, Germany; 2017 (revised July 2019).
5. Elecsys Syphilis assay [package insert]. Roche Diagnostics GmbH; Mannheim, Germany; 2019 (revised July 2019).

Table S1. Confirmatory methods by site.

Assay	Confirmatory method	Study site		
		Essen	Düsseldorf	Regensburg
Anti-HBc	Assay	ARCHITECT Anti-HBc immunoassay on an i2000sr instrument (Abbott Laboratories, Des Plaines, Illinois, USA)	CENTAUR Anti-HBc immunoassay (Siemens, München, Germany)	Enzygnost Anti-HBc monoclonal on the BEP III System (Siemens, München, Germany)
	Immunoblot	NA	NA	NA
	NAT	RealTime HBV Viral Load assay on the m2000 RealTime System (Abbott Laboratories, Des Plaines, Illinois, USA)	NA	RealTime HBV Viral Load assay on the m2000 RealTime System (Abbott Laboratories, Des Plaines, Illinois, USA)
Anti-HCV	Assay	ARCHITECT Anti-HCV immunoassay on an i2000sr instrument (Abbott Laboratories, Des Plaines, Illinois, USA)	NA	NA
	Immunoblot	INNO-LIA HCV Score (Fujirebio Germany GmbH, Hannover, Germany)	INNO-LIA HCV Score (Fujirebio Germany GmbH, Hannover, Germany)	INNO-LIA HCV Score (Fujirebio Germany GmbH, Hannover, Germany)
	NAT	RealTime HCV Viral Load assay on the m2000 RealTime System (Abbott Laboratories, Des Plaines, Illinois, USA)	NA	RealTime HCV Viral Load assay on the m2000 RealTime System (Abbott Laboratories, Des Plaines, Illinois, USA)
HIV	Assay	ARCHITECT HIV Ag/Ab immunoassay on an i2000sr instrument (Abbott Laboratories, Des Plaines, Illinois, USA)	NA	NA
	Immunoblot	INNO-LIA HIV I/II Score (Fujirebio Germany GmbH, Hannover, Germany)	INNO-LIA HIV I/II Score (Fujirebio Germany GmbH, Hannover, Germany)	INNO-LIA HIV I/II Score (Fujirebio Germany GmbH, Hannover, Germany)
	NAT	RealTime HIV-1 Viral Load assay on the m2000 RealTime System (Abbott Laboratories, Des Plaines, Illinois, USA)	NA	RealTime HIV-1 Viral Load assay on the m2000 RealTime System (Abbott Laboratories, Des Plaines, Illinois, USA)
HBsAg	Assay	ARCHITECT HBsAg immunoassay on an i2000sr instrument (Abbott Laboratories, Des Plaines, Illinois, USA)	NA	HBsAg Qualitative II Confirmatory assay on an i1000sr instrument (Abbott Laboratories, Des Plaines, Illinois, USA)
	Immunoblot	NA	NA	NA
	NAT	RealTime HBV Viral Load assay on the m2000 RealTime System (Abbott Laboratories, Des Plaines, Illinois, USA)	NA	RealTime HBV assay on the m2000 RealTime System (Abbott Laboratories, Des Plaines, Illinois, USA)
Syphilis	Assay	NA	NA	SERODIA TPPA (Fujirebio Inc., Tokyo, Japan), Rapid-Plasma-Reagin (RPR), FTA-Abs
	Immunoblot	NA	NA	Treponema IgG/IgM (Mikrogen, Neuried, Germany)
	NAT	NA	NA	NA

Abbreviations: HBc - hepatitis B core antigen, HBsAg - hepatitis B surface antigen, HCV - hepatitis C virus, HIV - human immunodeficiency virus, NA - not applicable.