Atellica VTLi Patient-side Immunoassay Analyzer Clinical Compendium

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Atellica VTLi Patient-side Immunoassay Analyzer Publication Compendium

This compendium was compiled to provide a reference for journal articles that have been published for Atellica VTLi Patient-side Immunoassay Analyzer and hs-cTnI assay.

These articles were published in various journals from 2020 through 2024. Entries are intended to be used as technical tools to validate the capabilities of Atellica VTLi analyzer and assays. Entries are for informational purposes only. Comments concerning the compendium or its contents may be directed to your local representative from Siemens Healthineers.

Title of Publication	System/Assay Cited	Overview/Conclusions	Author	Journal	Year
Designation of High Sensitivity					
↗ Determination of sex-specific 99th percentile upper reference limits for a point-of-care high-sensitivity cardiac troponin I assay	• Atellica VTLi • Hs-cTnI	"Our findings show the novel POC Atellica VTLi hs-cTnI assay meets the designation of a 'high sensitivity' assay using heparinized plasma."	Apple et al.	Clin Chem Lab Med. 2021;59(9): 1574-8.	2021
↗ Point-of-care: roadmap for analytical characterization and validation of a high-sensitivity cardiac troponin I assay in plasma and whole blood matrices	• Atellica VTLi • Hs-cTnI	"This analytical roadmap showed high-sensitivity performance, good analytic characteristics, and excellent PL and WB agreement for the Atellica VTLi hs-cTnI POC system."	Christenson et al.	J App Lab Med. 2022;7(4):971-88.	2022
Equivalent Performance on Available Sample Types					
↗ Point-of-care: roadmap for analytical characterization and validation of a high-sensitivity cardiac troponin I assay in plasma and whole blood matrices	• Atellica VTLi • Hs-cTnI	"This analytical roadmap showed high-sensitivity performance, good analytic characteristics, and excellent PL and WB agreement for the Atellica VTLi hs-cTnI POC system."	Christenson et al.	J App Lab Med. 2022;7(4):971-88.	2022
↗ Point-of-care high-sensitivity troponin-I analysis in capillary blood for acute coronary syndrome diagnosis	• Atellica VTLi • Hs-cTnI	"The POC Atellica VTLi ... for high-sensitive troponin I analysis shows equivalent results for all sample types, including capillary blood. No clinically relevant differences were observed between capillary POC and central laboratory results."	Bruinen et al.	Clin Chem Lab Med. [online] 2022;60(10): 1669-74.	2022
Equivalence in Diagnostic Accuracy to Central Lab					
↗ Diagnostic performance of a rapid, novel, whole blood, point of care high-sensitivity cardiac troponin I assay for myocardial infarction	• Atellica VTLi • Atellica IM • Abbott ARCHITECT • Hs-cTnI	"The POC, whole blood Atellica VTLi hs-cTnI assay demonstrated comparable diagnostic accuracy for MI to central laboratory assays using 99th percentiles."	Gunsolus et al.	Clin Biochem. 2022; 105-106:70-4.	2022
↗ Imprecision and real-time clinical performance of a whole blood high sensitivity point of care troponin i: ready for prime time?	• Atellica VTLi • Hs-cTnI • Hs-cTnT	"Clinical performance of the VTLi POC assay was acceptable and equivalent to CL hs-cTnT."	Hatherley et al.	European Heart Journal, Volume 45, Issue Supplement_1, October 2024, ehae666.1598,	2023
Analytical Performance					
↗ Analytical performance comparing Siemens whole blood point of care Atellica VTLi to the central laboratory plasma Atellica IM high-sensitivity cardiac troponin I assays	• Atellica VTLi • Atellica IM • Hs-cTnI	"The findings from this study validated a moderate to good concordance and correlation between the WB, POC Atellica VTLi hs-cTnI assay and the central laboratory plasma Atellica IM hs-cTnI assay results predicated on 99th percentile overall and sex-specific URLs, despite the lack of standardization between cTnI assays."	Xiong-Hang et al.	Clin Biochem. 2023;114:79-85.	2023

Spotlight article

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Title of Publication	System/Assay Cited	Overview/Conclusions	Author	Journal	Year
Analytical Performance					
↗ Analytical verification of the Atellica VTLi point of care high sensitivity troponin I assay	• Atellica VTLi • Beckman Coulter Access • Roche Cobas 801 • Siemens Healthineers Atellica IM • Abbott Alinity • Hs-cTnI • Hs-cTnT	"Concordances between VTLi and laboratory assays were at least non-inferior to those between laboratory assays. Imprecision met manufacturer claims and was consistent with a high sensitivity assay. There is potential for hemolysis interference, highlighting the need for quality samples. The results support performance characteristics previously reported in validation studies, and the device offers acceptable performance for use within intended medical settings."	Florkowski et al.	Clinical Chemistry and Laboratory Medicine 63(2):433-439	2024
Clinical Evidence					
↗ Consequences of different cut-off values for high-sensitivity cardiac troponin for risk stratification of patients suspected for NSTE-ACS with a modified HEART score	• Atellica VTLi • Hs-cTnI • Roche COBAS h 232	"The modified HEART score, with different cut-off values based on different hs-cTn assays, seems to make the HEART score stronger and more reliable in prehospital risk stratification of patients with suspected NSTE-ACS. Although the number of patients at low risk for NSTE-ACS is decreasing based on this modified HEART score, sensitivity and negative predictive value increases in ruling out patients with suspected NSTE-ACS."	Tolsma et al.	Future Cardiol. 2023;19(10): 497-504.	2023
↗ URGENT 1.5: diagnostic accuracy of the modified HEART score, with fingerstick point-of-care troponin testing, in ruling out acute coronary syndrome	• POC from Siemens Healthineers • Hs-cTnI • Roche COBAS e 801 Hs-cTnT	"The modified HEART score, integrating capillary POC hs-cTnI results, is a promising tool for ruling out ACS in patients with chest pain presenting to the cardiac emergency department. These results encourage prospective investigation into the integration of fingerstick POC troponin testing in the modified HEART score in a pre-hospital setting."	Koper et al.	Neth Heart J. 2022;30:360–9.	2022
↗ Determination of a whole-blood single-test low-risk threshold for a point-of-care high-sensitivity troponin assay	• Atellica VTLi • Beckman Coulter DXI800 • Hs-cTnI	"From base dataset of 2090 ED presentations of suspected ACS, the group derived a safe low-risk troponin POC-hsTnI threshold in real-world circumstances for use only within established diagnostic pathways which incorporate time from symptom-onset and ECG [Sensitivity 99.2%, NPV 99.7]. At <7 ng/L measured ≥3 hours from symptom onset and with non-ischaemic ECG, the 35.8% of presentations is comparable to the 39.9% found using the Beckman assay. The <7 ng/L threshold should not be applied to all-comers in isolation (regardless of ECG and symptom-onset), because sensitivity falls."	Pickering et al.	EMJ, Research Letter, Mar 2024	2024

Spotlight article

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Clinical Evidence					
↗ Diagnostic performance of a point of care high sensitivity cardiac troponin I assay and single measurement evaluation to rule out and rule in acute coronary syndrome	• Atellica VTLi • Roche Cobas 8000 • Hs-cTnI • Hs-cTnT	"Atellica VTLi showed comparable diagnostic performance for myocardial infarction (MI) to the central laboratory assay. A single measurement at patient presentation in the ED using a derived <4 ng/L and >54 ng/L thresholds was efficient in rapidly and safely ruling out and ruling in acute MI, respectively. Our data suggest the possible use of this POC assay either in emergency department of urban medical center, either in rural hospital for triage and patient management."	De Iuliis et. al	Clinical Chemistry and Laboratory Medicine (CCLM), vol. 62, no. 11, 2024, pp. 2326-2334	2024
↗ Point-of-care high-sensitivity cardiac troponin in suspected acute myocardial infarction assessed at baseline and 2 h	• Atellica VTLi	"A 2-h algorithm using a POC hs-cTnI concentration enables safe and efficient risk assessment of patients with suspected AMI. The short turnaround time of POC testing may support significant efficiencies in the management of the large proportion of emergency patients with suspected AMI."	Cullen et al.	European Heart Journal, Volume 45, Issue 28, 21 July 2024, Pages 2508–2515	2024
↗ Diagnostic Performance of Point-of-Care High-Sensitivity Troponin in the Exclusion of Non-ST-Elevation Myocardial Infarction in the Emergency Department	• Atellica VTLi • Roche Elecsys • Beckman Coulter Access • Hs-cTnI • Hs-cTnT	"These results suggest that high-sensitivity troponin POCT devices offer comparable diagnostic performance to traditional laboratory methods for the diagnosis of NSTEMI in the emergency department, potentially speeding up clinical decisions and optimizing resource utilization. In conclusion, this study demonstrated that hs-cTn POCT is equally effective in ruling out NSTEMI, while providing results in a significantly shorter time compared to main laboratory hs-cTn determination."	Zalama-Sánchez et al.	J. Pers. Med. 2024, 14, 762	2024
↗ Emergency department use of a high-sensitivity point-of-care troponin assay reduces length of stay: an implementation study preliminary report	• Atellica VTLi • Beckman Coulter Access hs-cTnI • Hs-cTnI	"The deployment of a hs-cTn POC analyzer into a large ED safely reduced length of stay. If translatable to other EDs, this could represent an important advancement to patient care."	Pickering et al.	European Heart Journal. Acute Cardiovascular Care, Volume 13, Issue 12, December 2024, Pages 838–842	2024

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User Evaluation					
↗ High-sensitivity troponin on Atellica VTLi patient-side immunoassay analyzer (Siemens): evaluation, risk assessment and practicability	• Atellica VTLi • Hs-cTnI	"Atellica VTLi analytical performances for POC hs-cTnI troponin are validated with the reliability of traditional systems. This device fulfils all the requirements for a POC or a stat laboratory usage."	Beneteau-Burnat et al.	Clin Chem Lab Med. 2021;59 (Special Suppl): S94–S998.	2022
↗ Analytical and clinical performance evaluation of high sensitivity cardiac troponin I hs-cTnI measurement through point of care	• Atellica VTLi • Roche COBAS • Hs-cTnI • Hs-cTnT	"The study to date demonstrated a strong correlation between the troponins of the hs-cTnI Atellica VTLi and hs-cTnT Cobas® analyzers, in addition to safety and accuracy through studies with commercial controls."	Paula et al.	AACC poster	2023
↗ Point of care testing for high-sensitive troponin I testing: return of experience from a tertiary care hospital clinical laboratory	• Atellica VTLi • Roche COBAS • Hs-cTnI • Hs-cTnT	"Our results showed a good analytical performance of the Siemens Atellica VTLi POCT assay combined with a short TAT. In addition, a good concordance with the reference method was observed and the high majority of the users evaluated the usability of the instrument as satisfactory."	Gruson et al.	IFCC poster Clin Chem Lab Med. 2023;61(Special Suppl):S519.	2023
↗ Real-life evaluation of hypersensitive I-troponin on a point-of care analyzer in an emergency unit	• Atellica VTLi • Hs-cTnI	"This study confirms the feasibility of using a POCT analyzer in the emergency department, provided that it performs high sensitivity troponin. However, some data are missing to be able to use it in the framework of rapid algorithm. Finally, the implementation of POCT requires collaboration between biologists and emergency physicians in terms of organization and interpretation of values, for the overall benefit of the patient."	Mottin et al.	Annales de Biologie Clinique. 2023;81(2): 145-55. *(Abstract in English only)*	2023
Sample Stability					
↗ Atellica VTLi hs-cTnI assay shelf life, in-use stability and sample stability	• Atellica VTLi • Hs-cTnI	"Venous whole blood, capillary whole blood from fingerstick, and plasma samples showed sufficient stability for use in clinical practice. Furthermore, cartridge stability showed good stability, both in shelf life (18 months) and in-use stability."	Kemper et al.	Clin Chem Lab Med. 2023;61(Special Suppl):S512.	2023
Methodology (ongoing clinical studies)					
↗ Aiming towards evidence based interpretation of cardiac biomarkers in patients presenting with chest pain using point of care testing (WESTCOR-POC): study design	• Atellica VTLi • Hs-cTnI	"This is a prospective single-center randomized clinical trial aiming to include 1500 patients admitted to the ED with symptoms suggestive of ACS. Patients will receive standard investigations following the European Society of Cardiology 0/1h protocols for centralized hs-cTnT measurements or the intervention using a 0/1h POC hs-cTnI algorithm. Primary end-points are 1) Safety; death, myocardial infarction or acute revascularization within 30 days 2) Efficiency; length of stay in the ED, 3) Cost effectiveness; total episode cost, 4) Patient satisfaction, 5) Patient symptom burden and 6) Patients quality of life. Secondary outcomes are 12-months death, myocardial infarction or acute revascularization, percentage discharged after 3 and 6 h, total length of hospital stay and all costs related to hospital contact within 12 months."	Thulin et al.	Scand Cardiovasc J. 2023;57 (1):2272585.	2023

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Methodology					
↗ Methods of the pivotal trial of the Atellica VTLi point of care emergency department high sensitivity troponin evaluations	• Atellica VTLi • Hs-cTnI	"This prospective observational study will enroll ~1500 patients at ~20 U.S. Emergency Departments. After informed consent, adults (>21 years of age) with suspected ACS, and no prior enrollment in this study, will provide a fingerstick and venous blood sample within 2 h of ED presentation, >2 to ≤4 h, and >4 to ≤9 h (max. blood draw = 60 mL). HEART and EDACS scores will be prospectively documented. Capillary and venous whole blood will undergo Atellica VTLi assay testing. At 30 ± 3 days, patient mortality status, major adverse cardiac events, and rehospitalizations will be determined. A clinical endpoint adjudication committee, blinded to hs-cTnI VTLi result, will define the final diagnosis. Sensitivity, specificity, and predictive values will describe the assay performance."	Peacock et al.	Clin Biochem. 2023;121-122:110679.	2023
↗ Protocol for Improving Care by Faster risk-Stratification through use of high sensitivity point-of- care troponin in patients presenting with possible acute coronary syndrome in the Emergency department (ICare-FASTER): a stepped-wedge cluster randomized quality improvement initiative	• Atellica VTLi	"The aim of this pragmatic quality improvement initiative is to assess the impact of a hs POC-cTnI assay in real-life care in the EDs of multiple hospitals. We also aim to establish an optimized process for including POC-cTnI within clinical pathways to achieve effective implementation."	Pickering et al.	BMJ Open 2024 ;14:e083752	2024
Guidelines and Recommendations					
↗ Future application of point of care high-sensitivity cardiac troponin testing in the emergency department	• General POC hs-cTn	"Expediting the diagnostic pathway for patients with suspected acute myocardial infarction (AMI) could substantially reduce the burden on increasingly crowded Emergency Departments (EDs). While current pathways enable AMI to be 'ruled in' or 'ruled out' for the majority of patients within hours of arrival, the turnaround time of laboratory cardiac troponin (cTn) assays is often a rate-limiting step for clinical decision-making. Point of care (POC) cTn assays typically have turnaround times of <20 min and could facilitate rapid clinical decision-making at the patient's bedside, without requiring on-site laboratory testing."	Body et al.	Eur Heart J Acute Cardiovasc Care. 2022 Feb;11(2): 170-2.	2022

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