

Clinical Application of ISO and CEN/TS Standards for Liquid Biopsies – Information Everybody Wants but Nobody Wants to Pay for



- Journal : Clinical Chemistry (IF: 7.1)
- Date : May, 2024.
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Study Aim: To evaluate the implementation of ISO and CEN/TS standardized workflows for liquid biopsies, including CTC analysis, in a real-world clinical study of advanced prostate cancer patients.

Methods:

- Collected 659 blood samples from 25 advanced prostate cancer patients
- Followed ISO 20186-3:2019 and CEN/TS 17390-3:2020 standards for sample collection and processing
- Assessed CTC presence using AdnaTest on 129 samples
- CTC enrichment was also performed using the CytoGen Smart Biopsy Cell Isolator on ACD-A tubes (tubes 3-4 of each blood series)
- Evaluated impact of hemolysis on CTC detection
- Documented detailed preanalytical parameters per standards

Key Findings Related to CTCs:

- 65.9% of samples were CTC-positive by AdnaTest
- CTCs were detected in both hemolytic (68.2%) and non-hemolytic (64.7%) samples
- The CytoGen Smart Biopsy Cell Isolator was used for CTC enrichment on ACD-A tubes (tubes 3-4) In 9.1% (23/252) of these samples, issues with blood coagulation were encountered.
- 9.1% of samples for CTC enrichment had issues with blood coagulation

Conclusions:

- ISO and CEN/TS standards can be successfully implemented in a clinical liquid biopsy study
- Hemolysis did not significantly impact CTC detection rates
- CTCs could be identified in hemolytic blood samples
- Adherence to standards provides reassurance of sample quality for CTC analysis, even in hemolytic samples

The study demonstrates that following rigorous preanalytical standards allows for reliable CTC analysis in clinical samples, including those affected by hemolysis.

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Cancer Diagnostics

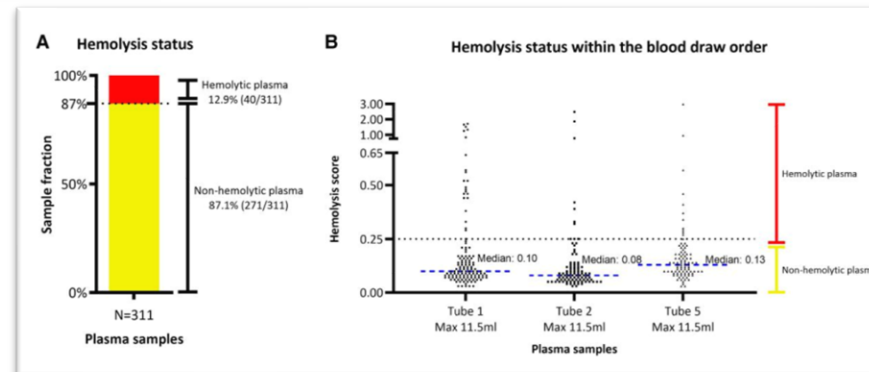
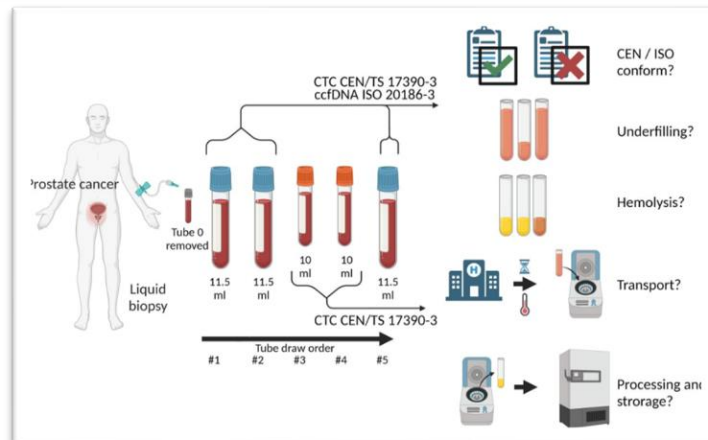
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- Study of Clinical liquid biopsy using ctDNA and CTCs
- Evaluation 659 peripheral blood samples from advanced prostate cancer patients
- Bridging the gap between theoretical standards and practical application in clinical settings

New standard of liquid biopsy using CTCs

• Human blood processing for Large-scale implementation



The research conducted by Professor Amin at the Medical University of Graz in Austria is exploring benchmarks in a clinical setting for liquid biopsy using CytoGen's platform.

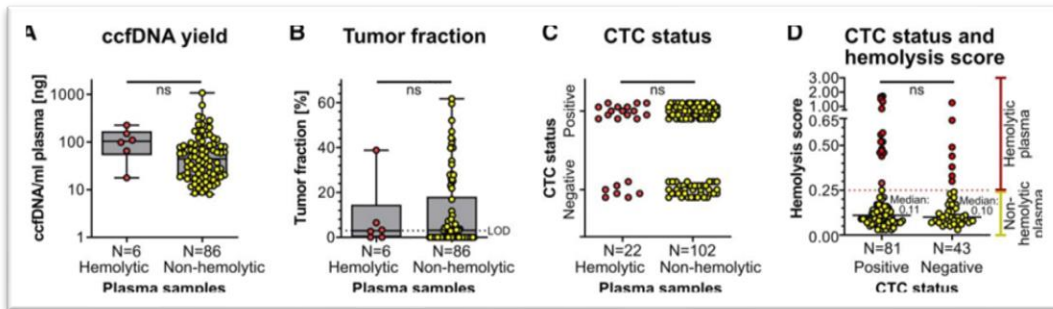


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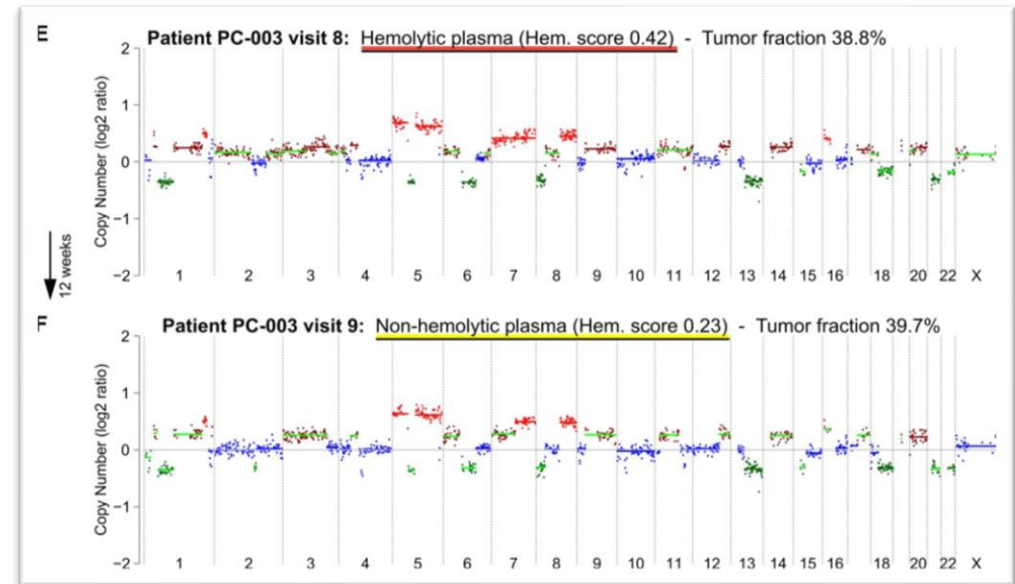
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- Evaluation of ccf DNA and CTCs in patient plasma samples

Spectroscopically measured hemolysis score of CTC samples



Plasma sequencing copy number profile of a hemolytic sample



- Comprehensive evaluation of ISO and CEN/TS standards for liquid biopsy.
- Proposing applicability in clinical settings.
- Providing a comprehensive perspective that considers both ctDNA and CTC.