

Zinc**Alliance Application Sheet**

Sentinel Diagnostics
Zinc Assay Application Sheet

For the Atellica® CH Analyzer

Refer to the appropriate Instructions for Use for information regarding these reagents. Also refer to Loading Atellica Alliance Application Assay Reagents on the CH Analyzer in Atellica® Solution Online Help for additional instructions.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

The parameters defined in this application sheet have been developed by Siemens Healthcare Diagnostics to optimize product performance. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results.

Materials

These reagents are qualified for use with the Liquid Standard (calibrator) included in the kit. Other material may be used for quality control purposes.

These reagents are for serum/plasma use only.

REF Sentinel	SMN Siemens	PRODUCT
17640H	10317329	Zinc
N/A*	11097534	EMPTY Reagent Pack**
N/A*	11538114	EMPTY1 Reagent Pack**
N/A*	11538115	EMPTY2 Reagent Pack**

*Not Applicable

**Materials required but not provided.

Reagent Preparation, Storage, and Stability

Note: For reagent preparation, storage information, and full product details, refer to the Instructions for Use.

Reagent Pack Preparation and Stability

Preparation Instructions

Transfer the appropriate reagent volumes into EMPTY reagent packs (refer to Table 1).

For instrument stability information refer to Table 2.

Table 1 – Reagent Pack Information

Contents	Number of Tests
Pack 1 Well 1 (W1) 20 mL of Zn R1* Well 2 (W2) Empty	2 x 154
Pack 2 Well 1 (W1) 5 mL of Zn R2* Well 2 (W2) Empty	

*Do not adjust required fill volumes, otherwise a system error may be generated.

Refer to the online help for instructions on loading operator-filled empty reagent packs.

Assay parameters have been predetermined in the instrument software. The reagent pack must be manually loaded on the Atellica Analyzer.

Zinc**Alliance Application Sheet****Table 2 - Calibration and Stability**

Pack Calibration	Lot Calibration	Onboard Stability
34 days	41 days	34 days

Important Information

For performance characteristics, intended use, limitations and a detailed description how to perform the method, refer to the Zinc REF 17640H Assay Instructions for Use.

Procedure

1. For serum/plasma, dispenses 50 µL primary sample and 200 µL of Atellica Sample Diluent into a dilution cuvette.
2. Dispenses 100 µL of Reagent 1 into a reaction cuvette.
3. Dispenses 25 µL of pre-diluted sample into a reaction cuvette.
4. Measures the absorbance after sample addition.
5. Dispenses 10 µL of Reagent 2 into a reaction cuvette.
6. Mixes and incubates the mixture at 37°C
7. Measures the absorbance after Reagent 2 addition.
8. Reports results

Calibration

Prepare a calibration by using the Zinc Calibrator. Recalibrate as indicated by control results.

Results

Results are reported in µg/dL.

Table 3 – TDEF Information

Assay	TDEF Code	Time to First Result
Zn	7086	9.7 minutes

Explanation of symbols

	In vitro Diagnostic Medical Device
	Catalogue number
	Batch code
	Contents of kit
	Caution, consult accompanying documents
	Consult instructions for use
	Use by (last day of the month)
	Contains sufficient for <n> tests
	Temperature limitation
	Manufacturer
	Made in Italy
	For use by or on the order of a physician only (applicable to USA classification only).

Note: changes in comparison to the previous version are indicated by a vertical bar in the text margin.

Atellica® is a trademark of Siemens Healthcare Diagnostics.
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CONTACT INFORMATION

For orders and technical support, contact Siemens Healthcare Diagnostics. Please contact your local representative.

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