

FibriTimer Zeta-1 Product Validation Publication

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RESEARCH ARTICLE

Performance Assessment of FibriTimer™ Zeta-1 for PT and APTT Testing

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ABSTRACT

The FibriTimer™ Zeta-1 (called ZETA1) is a new, semi-automated multipurpose Haemostasis system, indigenously developed featuring DUAL TECHNOLOGY. ZETA1 is designed and developed by a Bangalore MedTech Startup M/S Dfine Bio-innovations Pvt Ltd, keeping in mind the needs of smaller labs. ZETA1 has not yet been evaluated in India.

The objective of this study was to evaluate the ZETA1 performance for prothrombin time (PT), activated partial thromboplastin time (APTT), and international normalized ratio (INR) under local laboratory conditions.

For within run the CV% for normal control PT and APTT were 2.42 and 4.25 and 5.91 and 2.65 for abnormal control, respectively ⁴. For between runs on normal control, the CV% for PT and APTT were 0.76, 0.49, 2.34, and 0.99 for Abnormal control, respectively

The correlation coefficients of INR and APTT ratio between ZETA1 and CS-1600 were 0.96 and 0.81, respectively.

Standard Error of INR and APTT Ratio were, i.e., 0.023 and 0.076, respectively.

Keywords: New Coagulometer, FibriTimer™ Zeta-1 (called ZETA1) CS 1600 automated analyzer, performance assessment, screening PT and APTT tests.

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Conflict of interest: None

INTRODUCTION

Hemostasis is the physiological process that stops bleeding at the site of an injury while maintaining normal blood flow elsewhere in the circulation.¹ Multipurpose hemostatic systems have emerged as a promising strategy for managing acute bleeding. By integrating multiple hemostatic mechanisms into a single product, these systems aim to provide rapid and effective hemorrhage control across a spectrum of bleeding disorders.

STUDY – 1 (USING ZETA -1 OPTICAL METHOD) 14.05.2024

Methods

Control materials were used to evaluate the precision of ZETA1 and patient samples were used for comparability *vis-a-vis* the validated Sysmex® CS- 1600 analyzer (CS-1600).

Place of Study: Manipal Hospital

Manipal Hospital is a 600 bedded tertiary level care, technologically advanced infrastructure hospital situated in

the heart of Bangalore with the best of patient care facilities, equipment, diagnostic tests and treatment available under one roof. The hospital is equipped with 144 intensive care beds amongst ICUs, ICCUs, and NICUs and 20 modular State of the Art operation theatres with modern facilities.

Results

Precision study

Means, S.D., and %CV from within-run and between-run studies are presented in Table 1

Reference range and Mean Normal determination

No statistical outliers were observed in this study. PT and APTT results from normal subjects were normally distributed. Reference ranges for PT and APTT on Z-1 optical were 11-15 Sec and 24 to 36 seconds, respectively. The mean normal for PT was 13.5 seconds and Aptt was 29 seconds.

Both the ranges and mean were within the recommendations of the manufacturer.

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FibriTimer Zeta-1 Product Validation at Specialist Health, Bangalore

Date: 21st May 2024

Validation Report

Dfine Bioinnovations Pvt Ltd,
Bangalore - 560034

Subject: Evaluation of FibriTimer™ Zeta-1 for its Mechanical Testing with our automated coagulation system XL-1000C (Optical Testing) installed in our Central Laboratory.

Parameters: Prothrombin time (INR), activated partial thromboplastin time (APTT Ratio)

Instrument S/N: XL - 1000C: 133c2202002FibriTimer™ Zeta-1: FTZ1-2401048

Reagents and Control Material Used: QuikCoag from Biomedica Diagnostics, Canada.

Validation Methods Used: Precision Study using control material, Co-relation study with real samples.

Place of study: At our central laboratory

Approval for Study: Management Approval

Methodology: XL-1000C uses Optical Methodology for Coagulation testing and FibriTimer™ Zeta-1 uses both technology within its system. For validation purpose we chose to perform the tests on FibriTimer™ Zeta-1 by Mechanical method.

Statistical Software Used for data analysis: StatsDirect

RESULTS

Precision Studies: For Within run the CV% for normal control PT and APTT were 3.4 and 4.1 respectively.

Correlation Studies: Both INR, APTT Ratio between ZETA1 and XL-1000C shows good correlation.

The P value < 0.0001 for both and power of (5% significance) is >99.99%. The r2 values were 0.97 and 0.97 for INR and APTT Ratio respectively, indicating a positive and strong association.

Standard Error values were 0.021 and 0.021 for INR and APTT Ratio respectively,

Conclusion:

The performance of the Mechanical results on FibriTimer Zeta1 instrument was found to be satisfactory for PT and APTT testing. The correlation with our automated system and the Precision studies were in acceptable limits.

FibriTimer Zeta1 looks a perfect fit for small labs as a main unit and as a backup for midsize to large labs. The dual technology and the power backup features look promising addition.

Thankyou

For Specialist Health systems Pvt Ltd


Dr. Bharati Bhushan Chintawadagi
Pathologist - Lab Director



FibriTimer Zeta-1 Product Validation at Quantum Diagnostics



Date: 29th July, 2024

To,

Dfine Bioinnovations Pvt Ltd,

I Hub (B1), AMTZ Campus, Pragati Maidan,

VM Steel Project S.O, Vishakapatnam, AP - 530031

Objective: Validation study of FibriTimer™ Zeta-1 – A Single channel coagulation analyser system manufactured by M/S Dfine Bio innovations Pvt Ltd, Bangalore.

Method: FibriTimer™ Zeta-1 S/N: FTZI-2401012 performance on Optical mode was compared to our Laboratory Horiba Mecials, Yumezien G-200 S/N H50372-5018 with Optical methodology and following were the findings.

Accuracy Study:

The PT/INR results shows a co-relation with our Lab Instrument with a Correlation of $r_2 = 0.968$

The Aptt/Ratio results shows co-relation Correlation of $r_2 = 0.964$

With the boundary lines of the 95% confidence interval, the Standard Error was found to be 0.018 for PT/INR and 0.013 for APTT Ratio which is within acceptable limits of -2 to +2.

P value < 0.0001 for both and power of (5% significance) is >99.99%

Conclusion: Correlation shows a strong positive association

Precision Study:

A 10-control within run performed on FibriTimer™ Zeta-1 for both normal and abnormal controls on PT and Aptt on both Optical and Mechanical methods to check the total imprecision and we found that the SD and CV% for within run as well as between run was found to be well in acceptable limits and summarized as follows:

The Level 1 SD and CV% for PT OPTICAL were 0.30, 2.14 and Aptt were 0.34 and 1.40 respectively

The Level 1 SD and CV% for PT MECHANICAL were 0.43, 3.84 and Aptt were 0.48 and 2.02 respectively

The Level 2 SD and CV% for PT OPTICAL were 0.98, 3.31 and Aptt were 0.88 and 2.20 respectively

The Level 2 SD and CV% for PT MECHANICAL were 1.14, 3.48 and Aptt were 0.96 and 2.38 respectively

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