



Ref No: TBM/NZ-III/S-199/22-23
Date: 09/11/22

To
Jerath Path Labs and Allergy Testing Centre,
Jalandhar

Sub:- Regarding Factory Calibration of Instrument H 560

Dear Sir,

With reference to subject stated above we wish to confirm that Instrument H 560 having Serial no. K11042137003 installed at your Lab is factory calibrated and QC passed in September 2021 and requires further calibration on annual basis after installation at Customer end as per Company protocol.

Thanking you,

Yours faithfully,

For **TRANSASIA BIO-MEDICALS LTD.,**


Gian Chand
Area Sales Manager

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Tel Fax No: +91-172-4643837

E mail: g.chand@transasia.co.in

INSTALLATION & TRAINING REPORT

Customer Name : Jerath Path Lab
 Department : Path Lab.
 Address : 14 - Linka Road, Model Town, Jalandhar
 City : Jalandhar Pin : _____ State : Punjab
 Territory : Jalandhar 2 Zone : NZ III
 Telephone & Fax : _____ email : jerathpathlab@bommit.com
 Contact Person : Mr. Parshant Jerath MobileNo. : 9650112500
 Instrument Model : Elan 305 / H560 Sr. No. : 130180
 Installation Date : 2/12/2021 K11042137003

The above mentioned instrument has been satisfactorily installed by Service Engineer / Product Specialist of Transasia Bio-Medicals Ltd. Operational Training & User Maintenance of the instrument was provided to the following staff members on date (s) :

	Name (s)	Designation/ Dept.
1.	<u>Mr. Parshant Jerath</u>	<u>Doctor</u>
2.	_____	_____
3.	_____	_____

Test/ Parameters Demonstrated : _____

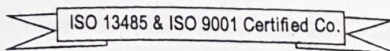
Customer Comments (If any) : _____

Engineer / Product Specialist : Engineer Customer Signature : [Signature]
 Signature : [Signature] Customer Name : Jatinder Kaur
 Name : Gurpreet Singh/Rampal Singh Designation : Lab Technician
 Date : 2/12/2021 Customer Seal : _____

Arbitration Clause

All disputes, differences, controversies and questions directly or indirectly arising at any time under, out of, in connection with or in relation to the payment of this instrument / reagents / service shall be referred to the sole arbitrator to be appointed by Transasia Bio-Medicals Limited under the Arbitration and Conciliation Act 1996. The venue and seat of arbitration shall be at Mumbai. The award rendered by the arbitrator(s) shall be final and binding upon both Parties.

www.transasia.co.in



TRANSASIA BIO-MEDICALS LTD.

CUSTOMER COPY

TRANSASIA HOUSE, 8 CHANDIVALI STUDIO ROAD, ANDHERI (E), MUMBAI - 400 072. TEL : 4030 9000 FAX : (022) 4030 9090 / 2857 3030 Email : transasia@transasia.co.in

DE_HI (011) 25732223 CHENNAI (044) 28227149 KOLKATA (033) 22157839 BANGALORE (080) 25568044 AHMEDABAD (079) 26407030



Erba Lachema s.r.o

DECLARATION OF CONFIRMITY and CALIBRATION



The undersigned Erba Diagnostics Ltd., Unit 4, Block K, Vantage Suites, Central Park, Leopardstown, Dublin 18, manufacturer of diagnostic devices, with Company Quality Management System in compliance with standard ISO 13485,

declares, that the device:

Name:H560

K11042137003

complies with all the essential requirements listed in Annex I of Directive 98/79/EC and obligations specified in Annex III, art. 2 – 5 of Directive 98/79/EC for In vitro Medical-Diagnostic Devices.

Therefore Erba Lachema s.r.o. declares and assures the following:

1. The a.m. device complies with the applicable provisions of Directive 98/79/EC.
2. The a.m. device is not included in the list A and B of the Annex II of Directive 98/79/EC.
3. The manufacturer declares to have established a procedure and to maintain it in order to assure the post-marketing surveillance, according to the Directive of 98/79/EC.
4. All mentioned products are Factory calibrated and Final QC passed at the time of release.

Date of issue:

Sep -2021

Manish Airan
Representative of Quality Management

Erba Diagnostics Ltd.
Unit 4, Block K, Vantage Sultes, Central Park, Leopardstown, Dublin 18
www.erbamannheim.com VAT Reg No : IE3517014VH

Certificate of Conformity and Calibration