

To Whom It May Concern

ISO 15189:2012 REQUIREMENTS REG. "CALIBRATION & VERIFICATION PROCEDURES"¹

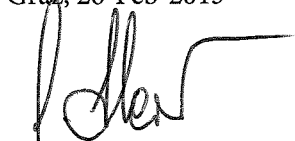
All Roche Diagnostics products which are distributed and for which a Free-Sales-Certificate is issued, are CE-marked. The In-Vitro-Diagnostics Directive of the European Union² requires for all CE marked products that the manufacturer assures compliance of the products with the requirements of the In-Vitro-Diagnostics Directive. This means that all processes in the development and manufacturing of Roche Diagnostics products are guided by a Quality Management System. Our Quality Management System is in compliance with the requirements from ISO 9001:2008³, ISO 13485:2003 + AC: 2007⁴, and QSReg⁵.

The mentioned regulations require that the production systems and measuring devices used are qualified and the manufacturing and test procedures are validated⁶. This status has to be assured by scheduled maintenance and by regular qualification resp. validation reviews and updates.

All physical quantities, calibrators and controls used in Roche Diagnostics systems are fully traceable to certified standards or reference materials. The performance of all Roche Diagnostics systems at the customer site is assured if regular QC measurements, cleaning and maintenance procedures as described in the instructions for use or service documentation are performed. By having controlled internal procedures and by running the tasks required in the respective user documentation, all Roche Diagnostics systems will perform as specified during their defined lifetime.

Additional calibration or verification procedures are NOT required of the user in order to assure the specified performances of every Roche Diagnostics system. Only if a user deviates from these manufacturer's recommendations does he have to establish site-specific calibration and verification procedures as part of his accreditation process.

Graz, 26-Feb-2013



Dr. Johann Harer

Head of Quality Management & Regulatory Affairs

¹ ISO 15189:2012, Medical laboratories - Requirements for quality and competence

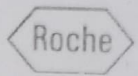
² Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

³ ISO 9001:2008, Quality Management Systems - Requirements

⁴ ISO 13485:2003 + Cor.1:2009, Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes)

⁵ Quality System Regulations, 21 CFR Part 820, requirements on medical devices

⁶ 21 CFR Part 809, 21 CFR Part 210, 21 CFR Part 11; GAMP 5 guideline; Annex 15 to the EU Guide to cGMP



| | | | |
|---------------------|--------------------------|-----------------------|------------------------|
| Case No. | CAS-0013301642 | Instrument Model | cobas 6000 c501 module |
| Order No. | ORD-0017161433 | Instrument Serial No. | 16Z0-07 |
| Contract Type | IN-COMPREHENSIVE | Finance Status | RENT |
| Lab/Inst./hosp.Name | Arth Diagnostics Pvt Ltd | | |
| Customer No. | 0052070145 | | |
| Contact Name : | Kishan Singh | | |
| Contact Number : | +919468703577 | | |
| Address : | Plot#4C,Apex Chamber, | | |
| City : | Udaipur | | |

| | | | |
|--------------------------|------------------|--------------------------|------------------|
| Call Received Date/Time: | 15.04.2021 16:45 | Call Attended Date/Time: | 27.06.2021 16:30 |
|--------------------------|------------------|--------------------------|------------------|

| | |
|----------|----------|
| Job Type | PM Visit |
|----------|----------|

| | |
|-----------------|---|
| Job Description | |
| Action Summary | Work done : Preventive Maintenance done, Calibration & Q.C. Done Customer Satisfaction Rating (1-5):5 |

Spare Part Replaced

| Part No | Parts Description | Batch No | Batch Expiry Date | Qty | Invoice Type |
|----------------------------|--|----------|-------------------|-----|----------------|
| 07783175001 ⁽¹⁾ | KIT MAINTENANCE 4 501/502 ⁽¹⁾ | | | 1 | Free of charge |
| 05521521001 ⁽¹⁾ | KIT MAINTENANCE 1 501/502 ⁽¹⁾ | | | 1 | Free of charge |

⁽¹⁾: Customer owned

Time Report

| Effective Visit Date : 27.06.2021 | | Complete Date : 28.06.2021 |
|-----------------------------------|---------------------------|----------------------------|
| Date | Type | Time |
| 2021.06.27 | Travel Time--Standard | 1 |
| 2021.06.27 | Working Time--Standard | 2 |
| 2021.06.28 | Quality Control--Standard | 0.5 |
| 2021.06.28 | Travel Time--Standard | 0.5 |
| 2021.06.28 | Working Time--Standard | 2 |
| Total: | | 6 |

| | |
|---|---|
| Customer's Signature Name : Singh Kishan | Service Engineer/Application Specialist Name : Manoj Vishwakarma |
| | |

| Daily | Month | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|-------|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | |
| Clean | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Sample probe & shield pipe ¹ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | |
| ISE sipper probe ¹ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | |
| ISE probe ¹ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | |
| Reagent probes ¹ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | |
| Cell rinse nozzles ⁴ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | |
| Drain port ⁴ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | |
| Perform: Daily pipe ⁵ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | |
| Tech | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| Photometer Check Reading at 340nm ² | |
|--|------------------|
| Day | Reading < 14,000 |
| 1 | 12,220 |
| 2 | 12,680 |
| 3 | 12,581 |
| 4 | 12,600 |
| 5 | 12,608 |
| 6 | 12,620 |
| 7 | 12,667 |
| 8 | |
| 9 | |
| 10 | |
| 11 | |
| 12 | |
| 13 | |
| 14 | |
| 15 | |
| 16 | |
| 17 | |
| 18 | |
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| 30 | |
| 31 | |

- Clean with disinfectant. Kodak Diagnostics recommends a cleaning solution such as Cavicide®. Do not use bleach.
- Replacement is based on photometer readings or power-on time. The life of the photometer lamp is guaranteed for 750 hours. Replace when photometer check reading at 340 nm is >14,000 or every 6 months, whichever comes first.
- Clean with alcohol.
- Clean with distilled or deionized water (DI).
- Daily Pipe is customized to your laboratory. Air Purge (All), Incubation Water Exchange, ISE Prime (All), Photometer Check and Essential Information Upload are required in Daily Pipe. Add Wash Reaction Parts if running DAT assays. For Wash Reaction Parts, ensure there are at least 58 mL of NaOH-D in the cobas c packs in the reagent compartment.

VERIFIED BY:
SECTION IN CHARGE :

 * HITACHI AUTOMATIC ANALYZER *

NAME
 S.NO.
 LOT

RANDOX-3
 C054055 0001-5
 1195UE

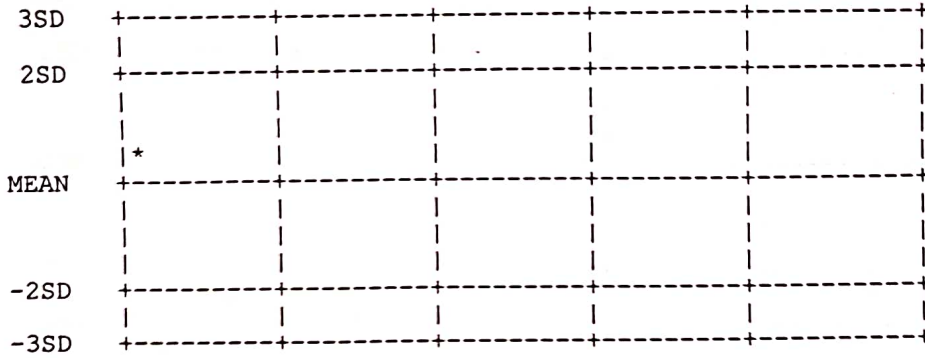
DATE 07/05/22 08:22:09
 OPERATOR ID bmserv

| TEST | RATIO COI/MES | RESULT | UNIT | MODULE | EXPECTED VALUE | ALARM |
|---------------|---------------|--------|-------|--------|----------------|-------|
| GLUC3 | | 282.2 | mg/dL | C | (238- 324) | |
| ALB2 | | 3.14 | g/dL | C | (2.60- 3.52) | |
| ALP2L | | 317 | U/L | C | (259- 351) | |
| ALTL | | 130.4 | U/L | C | (109- 163) | |
| ASTL | | 134.5 | U/L | C | (110- 164) | |
| BILD2 | | 2.393 | mg/dL | C | (1.89- 2.89) | |
| BILT3 | | 4.964 | mg/dL | C | (4.15- 6.35) | |
| CA2 | | 12.69 | mg/dL | C | (11.3- 13.7) | |
| CHOL | | 287.6 | mg/dL | C | (247- 321) | |
| CREJ | | 5.05 | mg/dL | C | (4.12- 6.20) | |
| TP2 | | 4.50 | g/dL | C | (3.53- 5.29) | |
| TRIGL | | 259.6 | mg/dL | C | (219- 301) | |
| UA | | 9.8 | mg/dL | C | (7.96- 10.32) | |
| UREA | | 124.7 | mg/dL | C | (104- 140) | |
| TEST039 - HDL | | 105.6 | mg/dL | C | (97- 130) | |

Individual QC Chart

07/05/22 15:37

MODULE C CONTROL RANDOX-3 LOT 1195UE TEST ALB2 UNIT g/dL



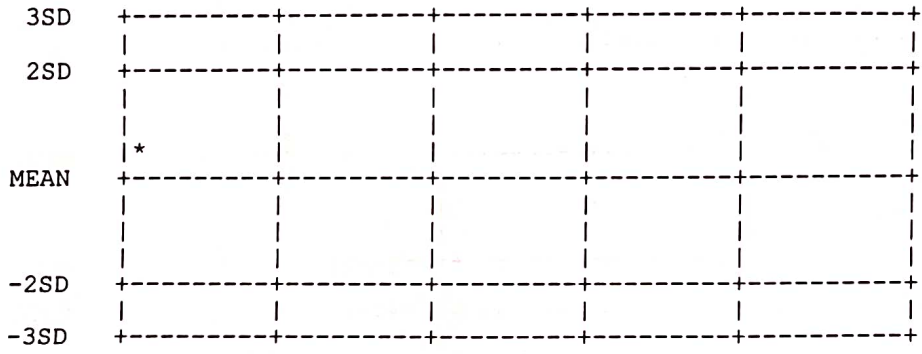
R.PACK LOT
 DATE TIME OP.ID RESULT UNIT DATE TIME OP.ID RESULT UNIT
 1 07/05 08:22 bmserv 3.14 g/dL

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN SD | CV(%) | RESULT |
|------|--------|---------|--------|--------|------|----|----------------|-------|--------|
| ALB2 | C | RANOX-3 | 1195UE | 3.06 | 0.23 | 16 | 3.105 0.061 | 1.96 | 3.14 |

Individual QC Chart

07/05/22 15:37

MODULE C CONTROL RANDOX-3 LOT 1195UE TEST ALP2L UNIT U/L

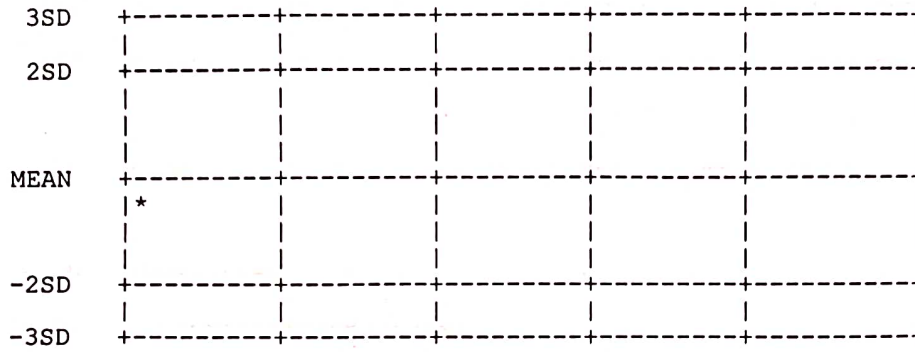


| R. PACK LOT | | | | | | | | | | | | |
|-------------|--------|---------|--------|--------|------|------|-------|--------|-------|--------|--|--|
| DATE | TIME | OP.ID | RESULT | UNIT | DATE | TIME | OP.ID | RESULT | UNIT | | | |
| 1 | 07/05 | 08:22 | bmserv | 317 | U/L | | | | | | | |
| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT | | |
| ALP2L | C | RANOX-3 | 1195UE | 305 | 23.0 | 16 | 316.0 | 5.2 | 1.65 | 317 | | |

Individual QC Chart

07/05/22 15:38

MODULE C CONTROL RANDOX-3 LOT 1195UE TEST **ALTL** UNIT U/L



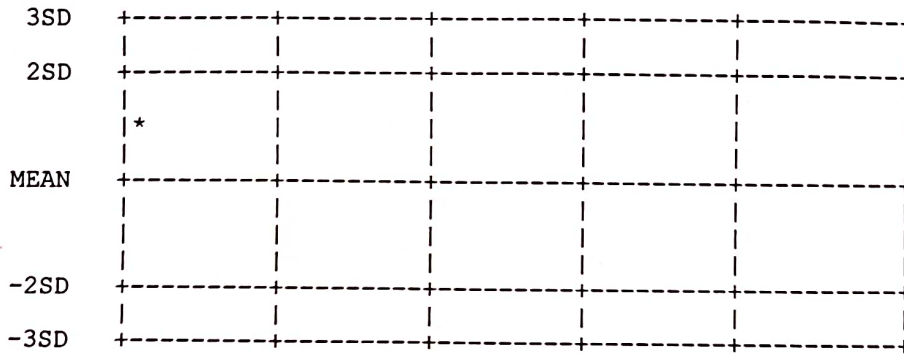
R.PACK LOT
 DATE TIME OP.ID RESULT UNIT DATE TIME OP.ID RESULT UNIT
 1 07/05 08:22 bmserv 130.4 U/L

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN SD | CV(%) | RESULT |
|------|--------|---------|--------|--------|------|----|----------------|-------|--------|
| ALTL | C | RANOX-3 | 1195UE | 136 | 13.5 | 16 | 135.44 3.00 | 2.22 | 130.4 |

Individual QC Chart

07/05/22 15:38

MODULE C CONTROL RANDOX-3 LOT 1195UE TEST AMYL2 UNIT U/L



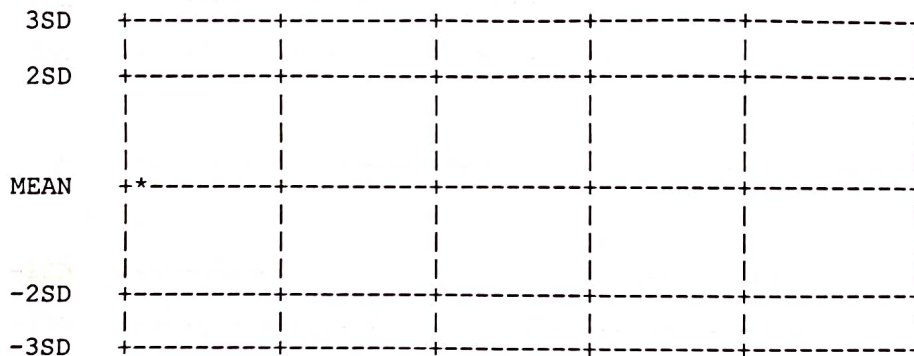
R. PACK LOT
 DATE TIME OP.ID RESULT UNIT DATE TIME OP.ID RESULT UNIT
 1 07/05 14:17 bmserv 270 U/L

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT |
|-------|--------|---------|--------|--------|------|---|-------|-----|-------|--------|
| AMYL2 | C | RANOX-3 | 1195UE | 249 | 19.0 | 2 | 266.5 | 4.9 | 1.84 | 270 |

Individual QC Chart

07/05/22 15:38

MODULE C CONTROL RANDOX-3 LOT 1195UE TEST **ASTL** UNIT U/L



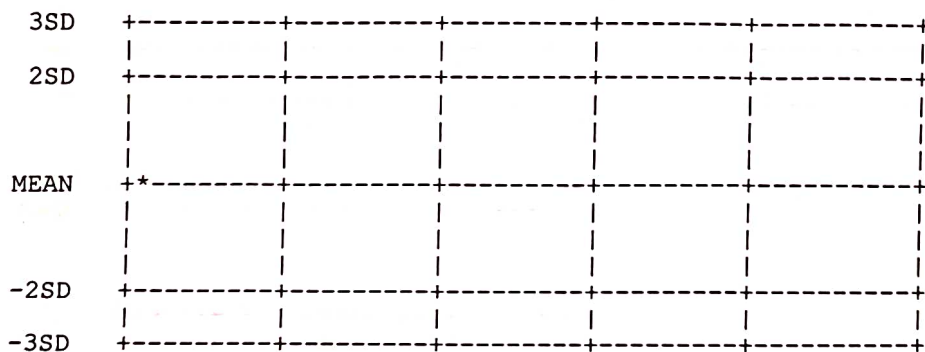
R. PACK LOT
 DATE TIME OP.ID RESULT UNIT DATE TIME OP.ID RESULT UNIT
 1 07/05 08:22 bmserv 134.5 U/L

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT |
|------|--------|---------|--------|--------|------|----|--------|------|-------|--------|
| ASTL | C | RANOX-3 | 1195UE | 137 | 13.5 | 17 | 137.44 | 2.11 | 1.54 | 134.5 |

Individual QC Chart

07/05/22 15:38

MODULE C CONTROL RANDOX-3 LOT 1195UE TEST BILD2 UNIT mg/dL



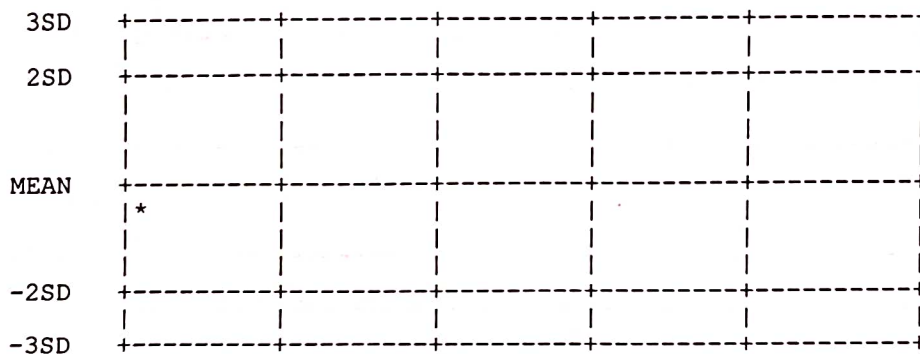
R. PACK LOT
 DATE TIME OP.ID RESULT UNIT DATE TIME OP.ID RESULT UNIT
 1 07/05 08:23 bmserv 2.393 mg/dL

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT |
|-------|--------|----------|--------|--------|------|----|--------|--------|-------|--------|
| BILD2 | C | RANDOX-3 | 1195UE | 2.39 | 0.25 | 16 | 2.3796 | 0.0894 | 3.76 | 2.393 |

Individual QC Chart

07/05/22 15:39

MODULE C CONTROL RANDOX-3 LOT 1195UE TEST **BILT3** UNIT mg/dL



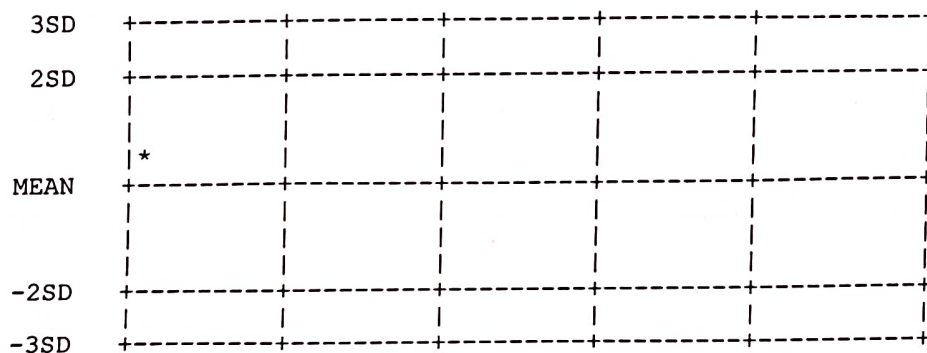
| R.PACK LOT | | DATE | TIME | OP.ID | RESULT | UNIT | DATE | TIME | OP.ID | RESULT | UNIT |
|------------|--|-------|-------|--------|--------|-------|------|------|-------|--------|------|
| 1 | | 07/05 | 08:23 | bmserv | 4.964 | mg/dL | | | | | |

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT |
|-------|--------|---------|--------|--------|------|----|--------|--------|-------|--------|
| BILT3 | C | RANOX-3 | 1195UE | 5.25 | 0.55 | 17 | 5.0055 | 0.1945 | 3.89 | 4.964 |

Individual QC Chart

07/05/22 15:39

MODULE C CONTROL RANDOX-3 LOT 1195UE TEST CA2 UNIT mg/dL



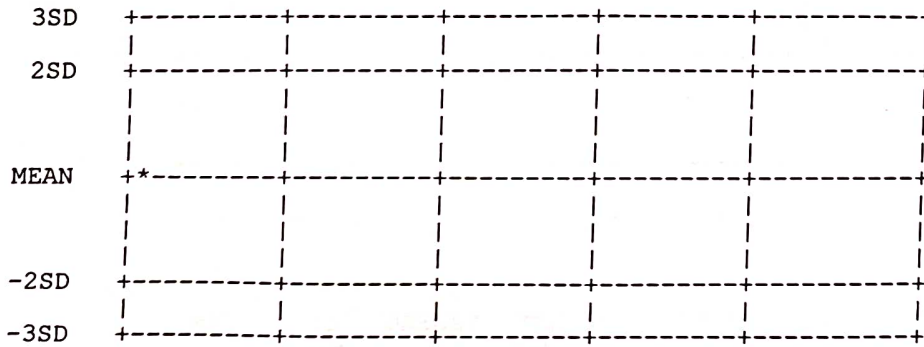
| R.PACK LOT | | DATE | TIME | OP.ID | RESULT | UNIT | DATE | TIME | OP.ID | RESULT | UNIT |
|------------|-------|-------|--------|-------|--------|------|------|------|-------|--------|------|
| 1 | 07/05 | 08:23 | bmserv | 12.69 | mg/dL | | | | | | |

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT |
|------|--------|---------|--------|--------|------|----|--------|-------|-------|--------|
| CA2 | C | RANOX-3 | 1195UE | 12.5 | 0.60 | 15 | 12.776 | 0.206 | 1.61 | 12.69 |

Individual QC Chart

07/05/22 15:39

MODULE C CONTROL RANDOX-3 LOT 1195UE TEST CHO2I UNIT mg/dL



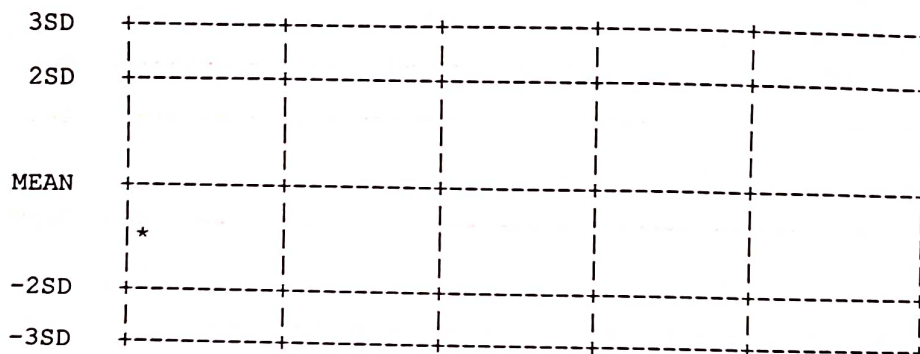
| R.PACK LOT | | DATE TIME | | OP.ID | RESULT | UNIT | DATE | TIME | OP.ID | RESULT | UNIT |
|------------|-------|-----------|--------|-------|--------|------|------|------|-------|--------|------|
| 1 | 07/05 | 08:23 | bmserv | 287.6 | mg/dL | | | | | | |

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT |
|-------|--------|---------|--------|--------|------|----|--------|------|-------|--------|
| CHO2I | C | RANOX-3 | 1195UE | 284 | 18.5 | 16 | 283.93 | 2.84 | 1.00 | 287.6 |

Individual QC Chart

07/05/22 15:39

MODULE C CONTROL RANDOX-3 LOT 1195UE TEST CK2 UNIT U/L



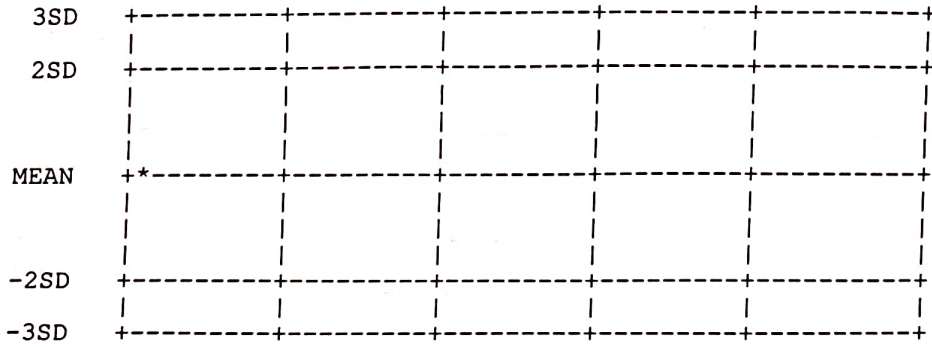
R.PACK LOT
 DATE TIME OP.ID RESULT UNIT DATE TIME OP.ID RESULT UNIT
 1 07/05 14:17 bmserv 475 U/L

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT |
|------|--------|---------|--------|--------|------|---|-------|------|-------|--------|
| CK2 | C | RANOX-3 | 1195UE | 527 | 47.5 | 2 | 467.5 | 10.6 | 2.27 | 475 |

Individual QC Chart

07/05/22 15:39

MODULE C CONTROL RANDOX-3 LOT 1195UE TEST CREJ2 UNIT mg/dL



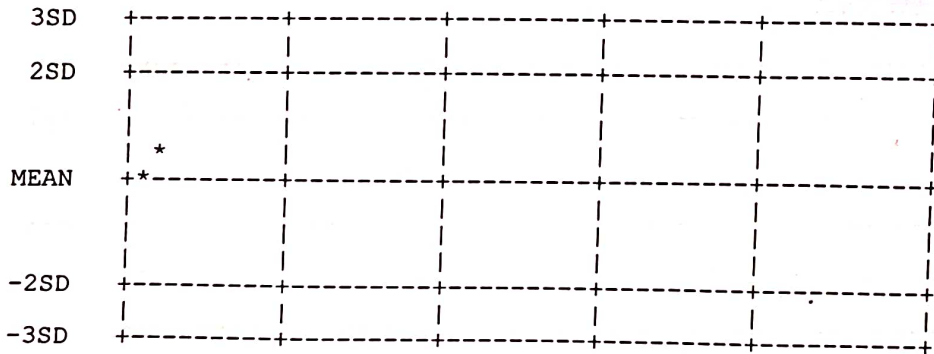
R.PACK LOT
 DATE TIME OP.ID RESULT UNIT DATE TIME OP.ID RESULT UNIT
 1 07/05 08:23 bmserv 5.05 mg/dL

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT |
|-------|--------|---------|--------|--------|------|----|-------|-------|-------|--------|
| CREJ2 | C | RANOX-3 | 1195UE | 5.16 | 0.52 | 17 | 5.031 | 0.124 | 2.46 | 5.05 |

Individual QC Chart

07/05/22 15:40

MODULE C CONTROL RANDOX-3 LOT 1195UE TEST **GLUC3** UNIT mg/dL



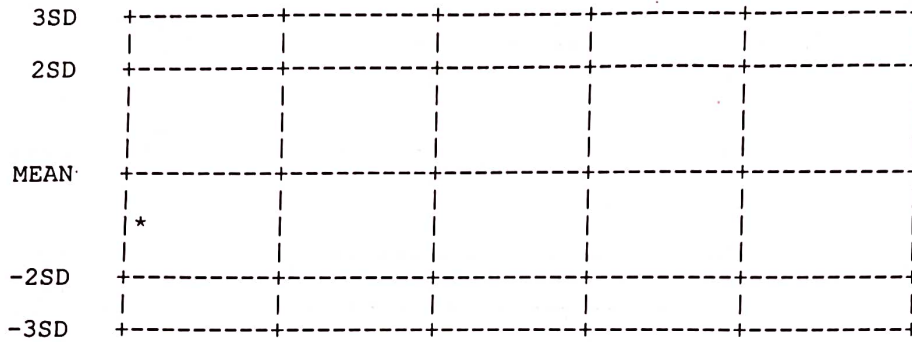
| R. PACK LOT | | DATE | TIME | OP.ID | RESULT | UNIT | DATE | TIME | OP.ID | RESULT | UNIT |
|-------------|--|-------|-------|--------|--------|-------|-------|-------|--------|--------|-------|
| 1 | | 07/05 | 08:22 | bmserv | 282.2 | mg/dL | 07/05 | 15:22 | bmserv | 291.7 | mg/dL |

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT |
|-------|--------|---------|--------|--------|------|----|--------|------|-------|--------|
| GLUC3 | C | RANOX-3 | 1195UE | 281 | 21.5 | 16 | 284.90 | 4.39 | 1.54 | 291.7 |

Individual QC Chart

07/05/22 15:40

MODULE C CONTROL RANDOX-3 LOT 1195UE TEST HDLC4 UNIT mg/dL



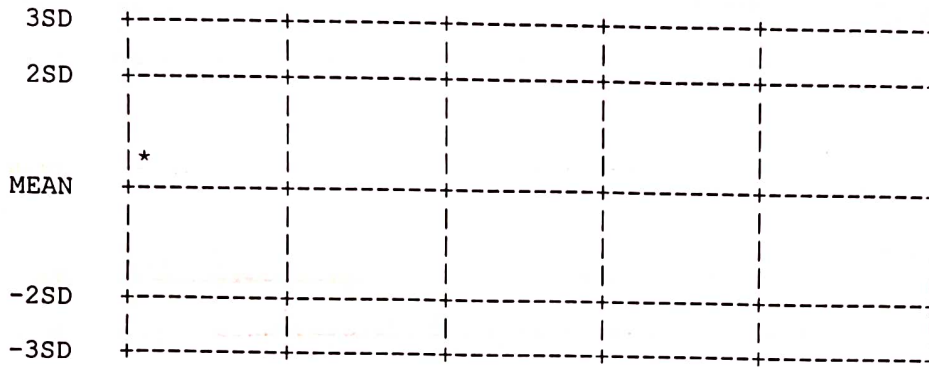
R.PACK LOT
 DATE TIME OP.ID RESULT UNIT DATE TIME OP.ID RESULT UNIT
 1 07/05 08:23 bmserv 105.6 mg/dL

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT |
|-------|--------|---------|--------|--------|------|----|--------|------|-------|--------|
| HDLC4 | C | RANOX-3 | 1195UE | 113 | 8.25 | 16 | 104.29 | 1.57 | 1.51 | 105.6 |

Individual QC Chart

07/05/22 15:40

MODULE C CONTROL RANDOX-3 LOT 1195UE TEST PHOS2 UNIT mg/dL



R. PACK LOT

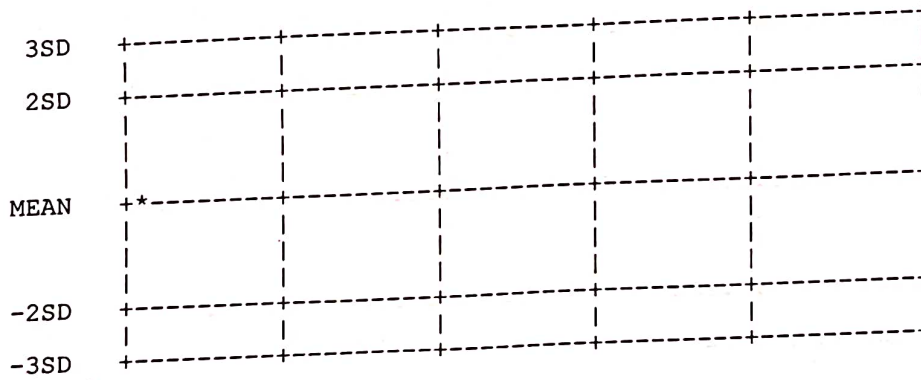
| DATE | TIME | OP.ID | RESULT | UNIT | DATE | TIME | OP.ID | RESULT | UNIT |
|---------|-------|--------|--------|-------|------|------|-------|--------|------|
| 1 07/05 | 14:17 | bmserv | 7.33 | mg/dL | | | | | |

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT |
|-------|--------|---------|--------|--------|------|---|-------|-------|-------|--------|
| PHOS2 | C | RANOX-3 | 1195UE | 7.19 | 0.54 | 2 | 7.115 | 0.304 | 4.27 | 7.33 |

Individual QC Chart

07/05/22 15:41

MODULE C CONTROL RANDOX-3 LOT 1195UE TEST TP2 UNIT g/dL

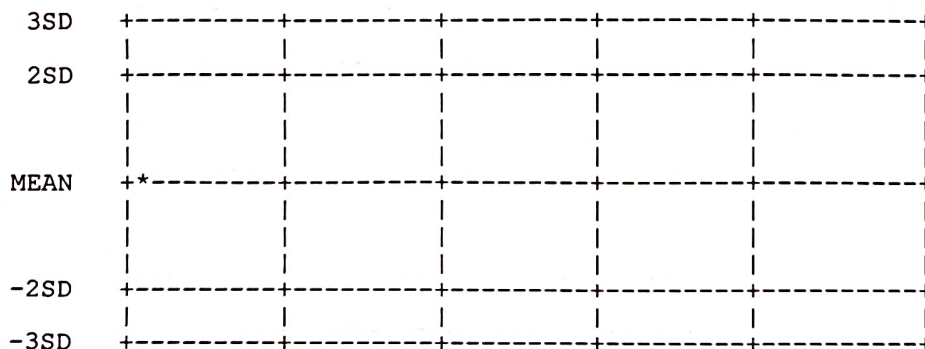


| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT |
|------|--------|---------|--------|--------|------|----|-------|-------|-------|--------|
| 1 | 07/05 | 08:23 | bmserv | 4.50 | g/dL | | | | | |
| TP2 | C | RANOX-3 | 1195UE | 4.41 | 0.44 | 16 | 4.514 | 0.071 | 1.57 | 4.50 |

Individual QC Chart

07/05/22 15:41

MODULE C CONTROL RANDOX-3 LOT 1195UE TEST TRIGL UNIT mg/dL



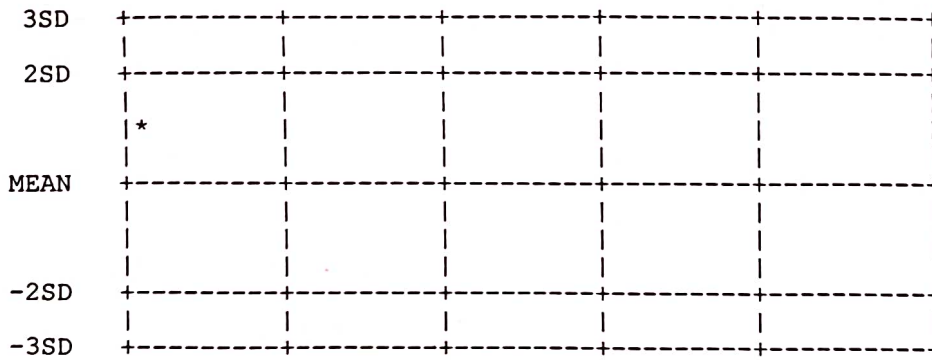
R.PACK LOT
 DATE TIME OP.ID RESULT UNIT DATE TIME OP.ID RESULT UNIT 1
 1 07/05 08:23 bmserv 259.6 mg/dL

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT |
|-------|--------|---------|--------|--------|------|----|--------|------|-------|--------|
| TRIGL | C | RANOX-3 | 1195UE | 260 | 20.5 | 16 | 257.62 | 3.83 | 1.49 | 259.6 |

Individual QC Chart

07/05/22 15:41

MODULE C CONTROL RANDOX-3 LOT 1195UE TEST UA2 UNIT mg/dL

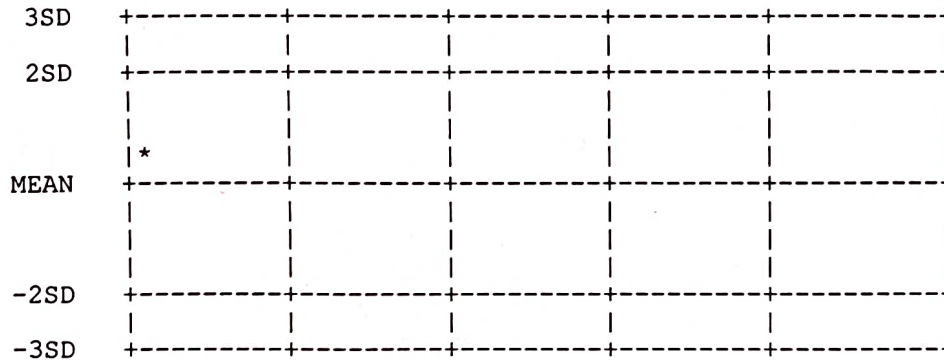


| R.PACK LOT | | | | | | | | | | | |
|------------|--------|---------|--------|--------|-------|------|-------|--------|-------|--------|--|
| DATE | TIME | OP.ID | RESULT | UNIT | DATE | TIME | OP.ID | RESULT | UNIT | 41 | |
| 1 | 07/05 | 08:23 | bmserv | 9.8 | mg/dL | | | | | | |
| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT | |
| UA2 | C | RANOX-3 | 1195UE | 9.14 | 0.59 | 16 | 9.67 | 0.22 | 2.28 | 9.8 | |

Individual QC Chart

07/05/22 15:41

MODULE C CONTROL RANDOX-3 LOT 1195UE TEST UREAL UNIT mg/dL



R. PACK LOT
 DATE TIME OP.ID RESULT UNIT DATE TIME OP.ID RESULT UNIT :41
 1 07/05 08:23 bmserv 124.7 mg/dL

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT |
|-------|--------|---------|--------|--------|------|----|--------|------|-------|--------|
| UREAL | C | RANOX-3 | 1195UE | 122 | 9.0 | 17 | 129.52 | 3.27 | 2.52 | 124.7 |

 * HITACHI AUTOMATIC ANALYZER *

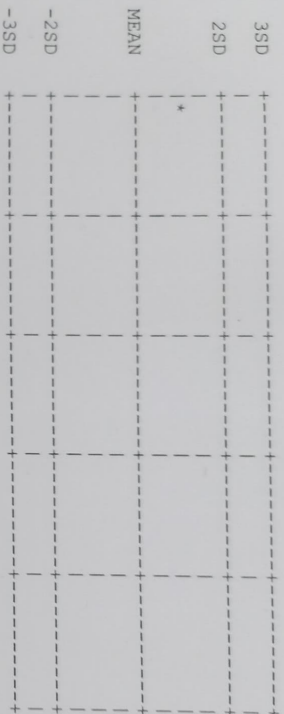
NAME RAND-BIO-2 DATE 28/06/21 09:14:11
 S.NO. C028059 0001-5 OPERATOR ID bmserv
 LOT 1390UN

| TEST | RATIO COI/MES | RESULT | UNIT | MODULE | ALARM |
|---------------|---------------|--------|-------|--------|--------|
| GLUC3 | | 104.1 | mg/dL | C | |
| ALB2 | | 4.60 | g/dL | C | |
| ALP2L | | 151 | U/L | C | |
| ALTL | | 32.3 | U/L | C | |
| ASTL | | 31.7 | U/L | C | |
| BILD2 | | 0.903 | mg/dL | C | |
| BILT3 | | 1.413 | mg/dL | C | |
| CA2 | | 8.62 | mg/dL | C | |
| CHOL | | 150.3 | mg/dL | C | |
| CREJ | | 1.57 | mg/dL | C | |
| GGT2 | | 52.2 | U/L | C | ReagEX |
| TP2 | | 5.87 | g/dL | C | |
| TRIGL | | 93.5 | mg/dL | C | |
| UA | | 6.0 | mg/dL | C | |
| UREA | | 46.3 | mg/dL | C | |
| PHOS | | 4.42 | mg/dL | C | |
| AMYLASE | | 85 | U/L | C | ReagEX |
| TEST039 - HDL | | 65.4 | mg/dL | C | |
| TEST042 | | 199.24 | U/L | C | |

Individual QC Chart

06/04/22 14:39

MODULE C CONTROL RAND-BIO-2 LOT 1390UN TEST ALB2 UNIT g/dL



R.PACK LOT
 DATE TIME OP.ID RESULT UNIT
 1*28/06 09:17 bmserv 4.60 g/dL

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT |
|------|--------|------------|--------|--------|------|-----|-------|-------|-------|--------|
| ALB2 | C | RAND-BIO-2 | 1390UN | 4.33 | 0.33 | 145 | 4.450 | 0.087 | 1.96 | 4.38 |

Individual QC Chart

06/04/22

14:40

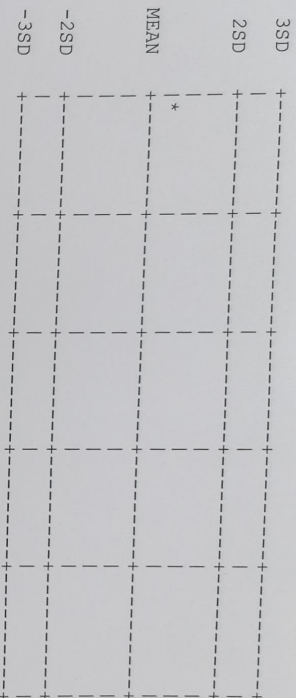
MODULE C

CONTROL RAND-BIO-2

LOT 1390UN

TEST ALP2L

UNIT U/L



R.PACK LOT

DATE TIME OP.ID RESULT UNIT
1 28/06 09:18 bmserv 151 U/L

DATE TIME OP.ID RESULT UNIT

TEST MODULE CONTROL IOT T.MEAN
ALP2L C RAND-BIO-2 1390UN 145

T.SD 11

N 367

MEAN SD 150.0

6.1

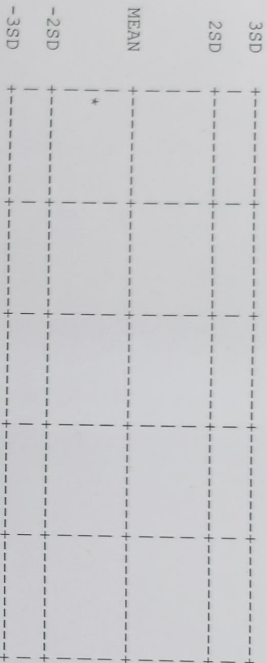
CV(%) 4.07

RESULT 149

MODULE C CONTROL RAND-BIO-2 LOT 1390UN

TEST ALLT

UNIT U/L



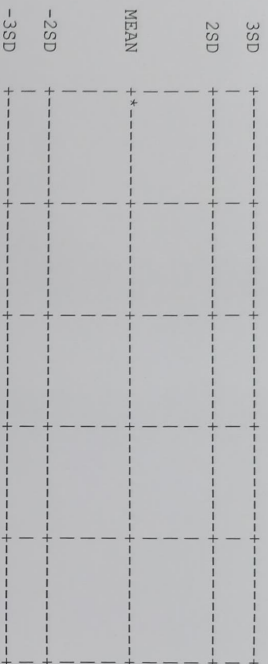
R.PACK LOT
 DATE TIME OP.ID RESULT UNIT DATE TIME OP.ID RESULT UNIT
 1 28/06 09:18 bmserv 32.3 U/L

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT |
|------|--------|------------|--------|--------|------|-----|-------|------|-------|--------|
| ALLT | C | RAND-BIO-2 | 1390UN | 36 | 3.50 | 392 | 33.93 | 1.77 | 5.22 | 32.2 |

Individual QC Chart

06/04/22 14:40

MODULE C CONTROL RAND-BIO-2 LOT 1390UN TEST **AMYL2** UNIT U/L



R. PACK LOT
 DATE TIME OP. ID RESULT UNIT DATE TIME OP. ID RESULT UNIT
 1 28/06 09:19 bmserv 85 U/L ReageX

TEST MODULE CONTROL LOT T.MEAN T.SD N MEAN SD CV(%) RESULT
 AMYL2 C RAND-BIO-2 1390UN 86.0 6.50 35 85.8 3.0 3.50 82

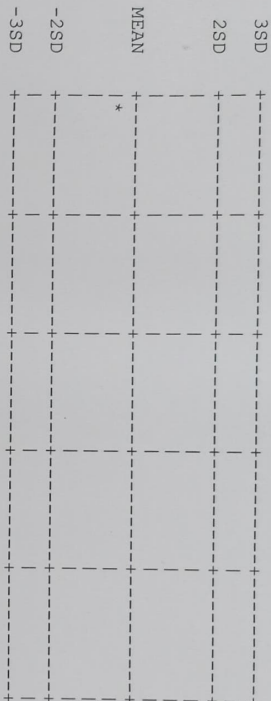
Individual QC Chart

06/04/22 14:40

MODULE C CONTROL RAND-BIO-2 LOT 1390UN

TEST ASTL

UNIT U/L



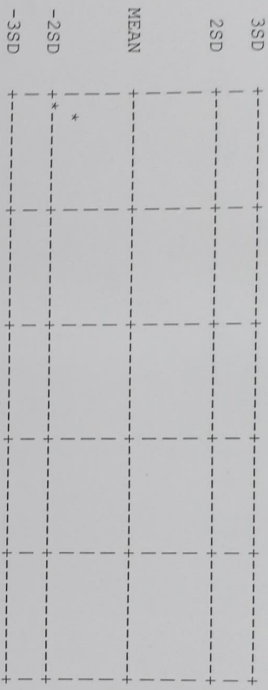
R.PACK LOT
 DATE TIME OP.ID RESULT UNIT
 1 28/06 09:18 bmserv 31.7 U/L

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN SD | CV(%) | RESULT |
|------|--------|------------|--------|--------|------|-----|---------|-------|--------|
| ASTL | C | RAND-BIO-2 | 1390UN | 34 | 3.50 | 365 | 31.32 | 3.58 | 30.3 |
| | | | | | | | 1.12 | | |

Individual QC Chart

06/04/22 14:41

MODULE C CONTROL RAND-BIO-2 IOT 1390UN TEST BIID2 UNIT mg/dL



R.PACK IOT

DATE TIME OP.ID RESULT UNIT DATE TIME OP.ID RESULT UNIT
 1 28/06 09:18 bmserv 0.903 mg/dL 28/06 17:11 bmserv 0.938 mg/dL

TEST MODULE CONTROL IOT T.MEAN T.SD N MEAN SD CV(%) RESULT
 BIID2 C RAND-BIO-2 1390UN 1.12 0.12 365 1.0199 0.0746 7.31 0.855

MODULE C CONTROL RAND-BIO-2 LOT 1390UN

TEST BILTS3

UNIT mg/dL

```

+-----+-----+-----+
3SD |-----|-----|-----|
+-----+-----+-----+
2SD |-----|-----|-----|
+-----+-----+-----+
MEAN |-----|-----|-----|
+-----+-----+-----+
| * |-----|-----|-----|
+-----+-----+-----+
-2SD |-----|-----|-----|
+-----+-----+-----+
-3SD |-----|-----|-----|

```

R.PACK LOT

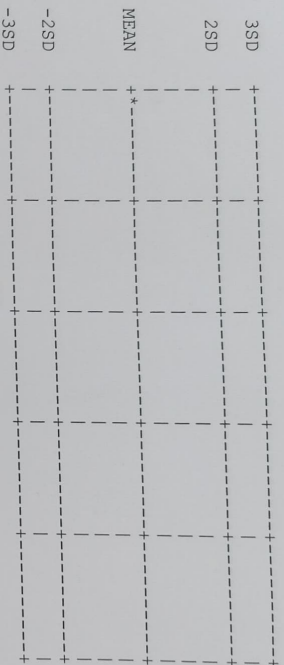
| DATE | TIME | OP.ID | RESULT | UNIT | DATE | TIME | OP.ID | RESULT | UNIT |
|------|-------|-------|--------|-------|------|------|-------|--------|------|
| 1 | 28/06 | 09:18 | bmserv | 1.413 | | | | | |

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT | UNIT |
|-------|--------|------------|--------|--------|------|-----|--------|--------|-------|--------|------|
| BILTS | C | RAND-BIO-2 | 1390UN | 1.59 | 0.17 | 371 | 1.5086 | 0.0845 | 5.60 | 1.427 | |

Individual QC Chart

06/04/22 14:42

MODULE C CONTROL RAND-BIO-2 LOT 1390UN TEST CHO2I UNIT mg/dL

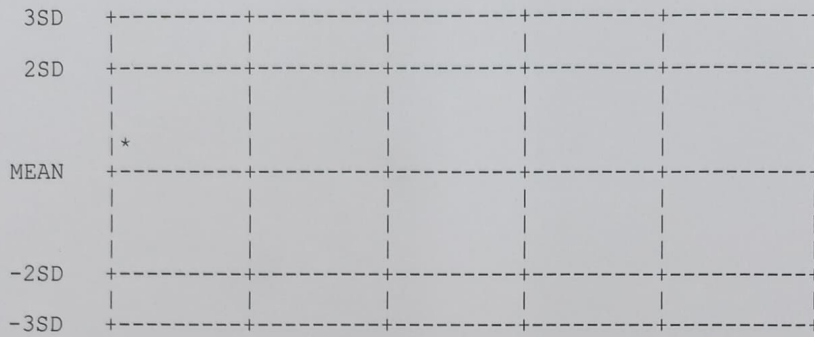


| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT | UNIT |
|------|--------|---------|--------|--------|-------|-----|--------|------|-------|--------|-------|
| 1 | 28/06 | 09:18 | bmserv | 150.3 | mg/dL | | | | | | |
| | | | | 152 | 9.50 | 371 | 149.90 | 4.31 | 2.88 | 150.8 | mg/dL |

Individual QC Chart

06/04/22 14:43

MODULE C CONTROL RAND-BIO-2 LOT 1390UN TEST CREJ2 UNIT mg/dL



R.PACK LOT
 DATE TIME OP.ID RESULT UNIT DATE TIME OP.ID RESULT UNIT
 1 28/06 09:19 bmserv 1.57 mg/dL

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT |
|-------|--------|------------|--------|--------|------|-----|-------|-------|-------|--------|
| CREJ2 | C | RAND-BIO-2 | 1390UN | 1.50 | 0.15 | 378 | 1.477 | 0.057 | 3.86 | 1.44 |

Individual QC Chart

06/04/22 14:43

MODULE C CONTROL RAND-BIO-2 LOT 1390UN TEST GLUC3 UNIT mg/dL



| R.PACK LOT | | DATE | TIME | OP.ID | RESULT | UNIT | DATE | TIME | OP.ID | RESULT | UNIT |
|------------|-------|-------|--------|-------|--------|------|-------|-------|--------|--------|-------|
| 1 | 28/06 | 09:17 | bmserv | 104.1 | mg/dL | | 28/06 | 16:52 | bmserv | 111.7 | mg/dL |

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT |
|-------|--------|------------|--------|--------|------|-----|--------|------|-------|--------|
| GLUC3 | C | RAND-BIO-2 | 1390UN | 111 | 8.30 | 387 | 106.02 | 6.18 | 5.83 | 106.1 |

Individual QC Chart

06/04/22 14:44

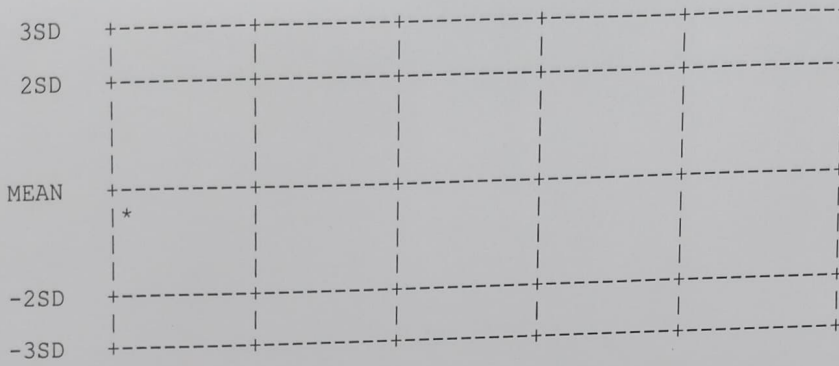
MODULE C

CONTROL RAND-BIO-2

LOT 1390UN

TEST HDLC4

UNIT mg/dL



R.PACK LOT
 DATE TIME OP.ID RESULT UNIT
 1 28/06 09:19 bmserv 65.4 mg/dL

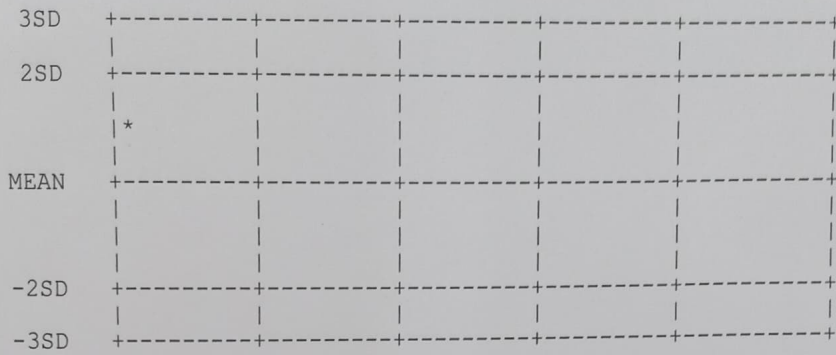
DATE TIME OP.ID RESULT UNIT

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT |
|-------|--------|------------|--------|--------|------|-----|-------|------|-------|--------|
| HDLC4 | C | RAND-BIO-2 | 1390UN | 69.1 | 5.20 | 360 | 67.68 | 2.53 | 3.74 | 67.0 |

Individual QC Chart

06/04/22 14:45

MODULE C CONTROL RAND-BIO-2 LOT 1390UN TEST PHOS2 UNIT mg/dL



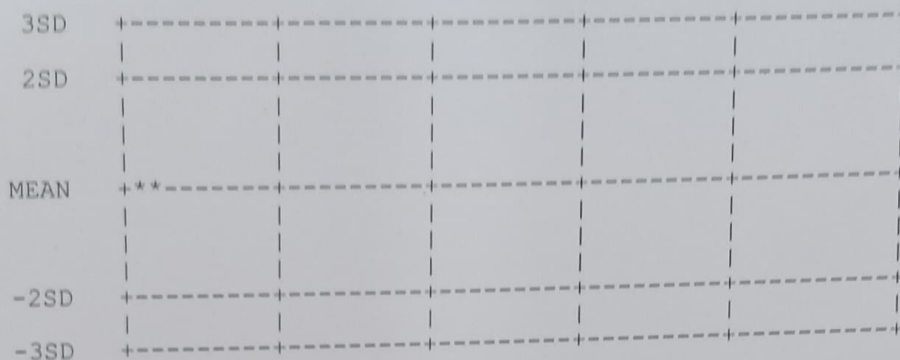
R.PACK LOT
 DATE TIME OP.ID RESULT UNIT DATE TIME OP.ID RESULT UNIT
 1 28/06 09:19 bmserv 4.42 mg/dL

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN SD | CV(%) | RESULT |
|-------|--------|------------|--------|--------|------|----|----------------|-------|--------|
| PHOS2 | C | RAND-BIO-2 | 1390UN | 4.15 | 0.31 | 38 | 4.242 0.093 | 2.19 | 4.21 |

Individual QC Chart

06/24/22 14:45

MODULE C CONTROL RAND-BIO-2 LOT 1390UN TEST TP2 UNIT g/dL

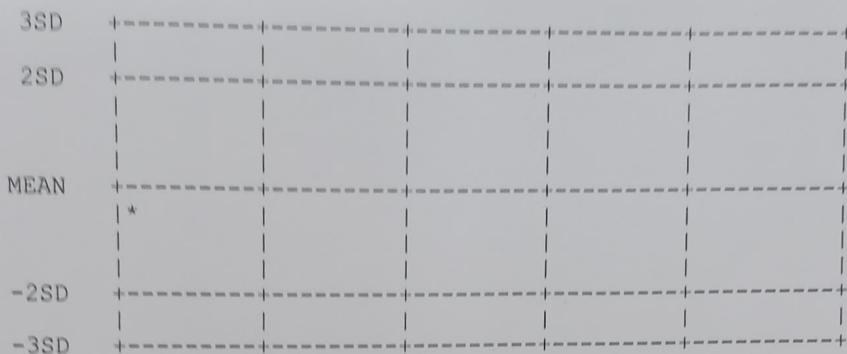


| R.PACK LOT | | DATE | TIME | OP.ID | RESULT | UNIT | DATE | TIME | OP.ID | RESULT | UNIT |
|------------|--------|------------|--------|--------|--------|-------|-------|--------|-------|--------|------|
| 1 | 28/06 | 09:18 | bmserv | 5.87 | g/dL | 28/06 | 11:56 | bmserv | 5.94 | g/dL | |
| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT | |
| TP2 | C | RAND-BIO-2 | 1390UN | 5.80 | 0.58 | 366 | 5.855 | 0.113 | 1.93 | 5.83 | |

Individual QC Chart

06/04/22 14:45

MODULE C CONTROL RAND-BIO-2 LOT 1390UN TEST TRIGL UNIT mg/dL



R. PACK LOT

| DATE | TIME | OP.ID | RESULT | UNIT | DATE | TIME | OP.ID | RESULT | UNIT |
|---------|-------|--------|--------|-------|------|------|-------|--------|------|
| 1 28/06 | 09:19 | bmserv | 93.5 | mg/dL | | | | | |

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN SD | CV(%) | RESULT |
|-------|--------|------------|--------|--------|------|-----|---------------|-------|--------|
| TRIGL | C | RAND-BIO-2 | 1390UN | 96.5 | 7.65 | 382 | 94.50 4.28 | 4.53 | 95.1 |

Individual QC Chart

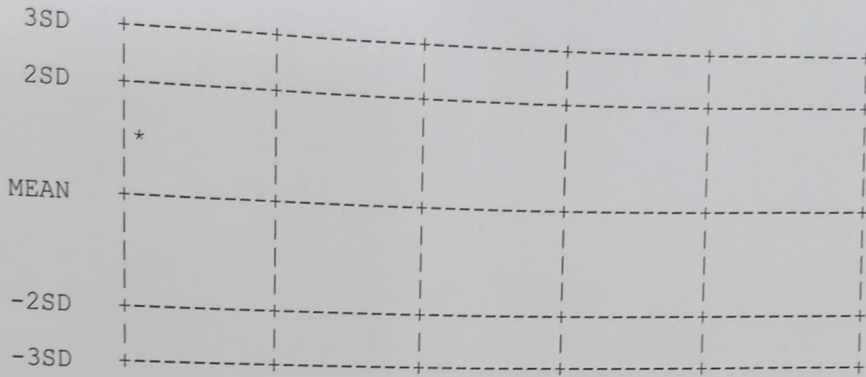
06/04/22 14:46

MODULE C

CONTROL RAND-BIO-2 LOT 1390UN

TEST UA2

UNIT mg/dL



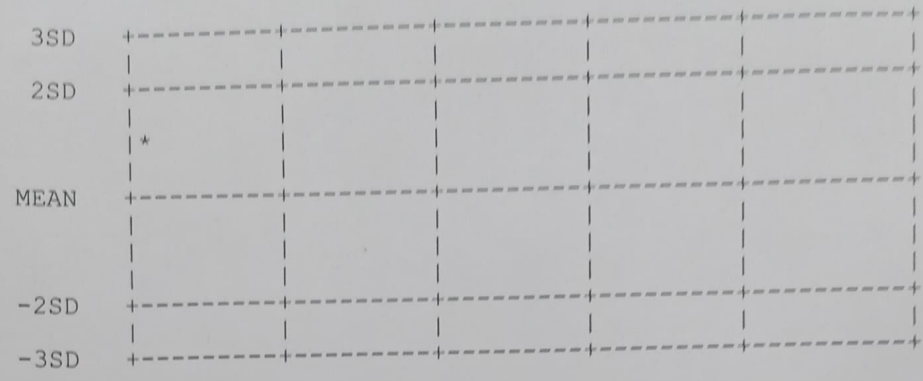
| R.PACK LOT | | DATE | TIME | OP.ID | RESULT | UNIT | DATE | TIME | OP.ID | RESULT | UNIT |
|------------|--|-------|-------|--------|--------|-------|------|------|-------|--------|------|
| 1 | | 28/06 | 09:19 | bmserv | 6.0 | mg/dL | | | | | |

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT |
|------|--------|------------|--------|--------|------|-----|------|------|-------|--------|
| UA2 | C | RAND-BIO-2 | 1390UN | 5.68 | 0.37 | 366 | 5.73 | 0.16 | 2.79 | 6.0 |

Individual QC Chart

06/04/22 14:46

MODULE C CONTROL RAND-BIO-2 LOT 1390UN TEST UREAL UNIT mg/dL



R. PACK LOT
 DATE TIME OP.ID RESULT UNIT
 1 28/06 09:18 bmserv 46.3 mg/dL

DATE TIME OP.ID RESULT UNIT
 T.SD N MEAN SD CV(%) RESULT
 3.15 384 44.35 1.99 4.49 43.9

| TEST | MODULE | CONTROL | LOT | T.MEAN | T.SD | N | MEAN | SD | CV(%) | RESULT |
|-------|--------|------------|--------|--------|------|-----|-------|------|-------|--------|
| UREAL | C | RAND-BIO-2 | 1390UN | 42.7 | 3.15 | 384 | 44.35 | 1.99 | 4.49 | 43.9 |