

Metropolis Healthcare Ltd., EQAS

KRSNAA DIAGNOSTICS LTD DASUYA (1044)

Outlier And Analyte Summary Report

Outlier Details For Cycle No 240104 and Sample No 02

Report Date : 10/07/2024

| Analyte | Instrument | Result Value | Standard Unit |
|---|------------|--------------|---------------|
| X Widal test - ParaTyphi A-H antigen (AH) | Manual | 1:160 | - |
| X Widal test - ParaTyphi B-H antigen (BH) | Manual | 1:80 | - |

Legend @ : Acceptable
X : Unacceptable
: Not Evaluated
⊙ Delayed Result Entry

Problem Classification: _____

Corrective Action: _____

Reviewed by: _____

Dated: _____

Instrument : Manual

| Analyte | Standard Unit | Result Value | Accepted Value |
|---|---------------|------------------|------------------|
| X Widal test - ParaTyphi A-H antigen (AH) | - | 1:160 | No Agglutination |
| X Widal test - ParaTyphi B-H antigen (BH) | - | 1:80 | No Agglutination |
| @ RPR (Syphilis Serology) | - | Non-reactive | Non-reactive |
| @ Dengue NS 1 | RU/ml | Negative | Negative |
| @ Widal test - Typhi O antigen (TO) | - | No Agglutination | No Agglutination |
| @ Widal test - Typhi H antigen (TH) | - | No Agglutination | No Agglutination |
| @ Dengue IgM | RU/ml | Negative | Negative |
| @ Dengue IgG | RU/ml | Negative | Negative |

Instrument : J Mitra

| Analyte | Standard Unit | Result Value | Accepted Value |
|----------|---------------|-------------------------|-------------------------|
| @ HBsAg | IU/mL | Reactive | Reactive |
| @ HCV | IU/mL | Non-reactive | Non-reactive |
| @ HIV Ab | S/CO | HIV-1/HIV-2 Ab Reactive | HIV-1/HIV-2 Ab Reactive |

Legend @ : Acceptable
 @ : Acceptable
 X : Unacceptable
 # : Not Evaluated
 ⓪ : Delayed Result Entry

| | |
|---------------------------------|---------|
| Total Parameters | 11 |
| Not Evaluated Parameters | 0 |
| Evaluated Parameters | 11 |
| Outlier Parameters (X) | 2 |
| EQAS Score Immunoassay Extended | 81.82 % |

Dr Puneet Nigam

Dr Puneet Kumar Nigam
 PT coordinator & Technical Manager, MHL EQAS
 Unit No. 409-416.
 Commercial Building - 1A
 Kohinoor Mall, Kirod Road, Kurla (W),
 Mumbai - 400070

Proficiency Testing Outlier Investigation Form

Laboratory Name : Krsnaa diagnostic HD Dasuva

Date 24/7/24 **Department** Pathology **Test Analyte** W/DAL **Reported Results** 1:160.

Acceptable Results
Not Acceptable

Sample receipt

- Was the kit received in good condition?
- Was the correct program/cycle received?
- Was the kit stored at the proper temperature following receipt?

| YES. | NO | NA |
|-------------------------------------|-------------------------------------|--------------------------|
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Sample Preparation:

Who Prepared sample? Kanchan Devi **Date Prepared** 10/7/24

- Was the correct reconstitution instruction followed (handling, time, temperature)?
- Was a volumetric Class A (or calibrated) pipette used for reconstitution?
- Was distilled or deionized water used for reconstitution?
- Was the sample mixed according to the package insert prior to testing?

| YES. | NO | NA |
|-------------------------------------|--------------------------|--------------------------|
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Sample Processing:

Who processed test? Kanchan Devi **Date of processing** 10/7/24

- Was the correct sample number tested?
- Was the sample at room temperature?
- Was the person running the test current in their training?
- Was the affected test run within the stability claim listed in the package insert

| YES | NO | NA |
|-------------------------------------|--------------------------|--------------------------|
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Reporting Results:

Who reported Results Kanchan Devi **Date reported.** 10/7/24

| | | | |
|--|----------------|-------------------------|--------------|
| Issued by : Vinod Lonkar <u>Vinod</u> | | Issue Date : 01.09.2023 | |
| Approved by : Dr. Manish Karekar <u>Manish</u> | | | |
| Doc No. GEN 03 | Version No : 1 | Amend No. -- | Amend Date . |

- Was the test configuration correct (instrument, method and reagent)?
- Have the results been reported correctly (match instrument print out)?
- Was the correct unit reported?
- Was the decimal symbol placed correctly when reported?
- Was the reported result within the instrument's linear range?
- Was the calculation of the reported result done correctly?

| YES | NO | NA |
|-------------------------------------|--------------------------|--------------------------|
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Internal QC:

- Was IQC within an acceptable range on the day that the EQAS sample was run?
- Where there any shifts or trends in IQC just before/after the EQAS sample was run?

| YES | NO | NA |
|-------------------------------------|--------------------------|--------------------------|
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

IQC on the day on EQAS sample

| | Reading | MEAN | SD | CV | Z Score |
|-----------|---------|-------|-------|-------|---------|
| Level-I | _____ | _____ | _____ | _____ | _____ |
| Level-II | _____ | _____ | _____ | _____ | _____ |
| Level-III | _____ | _____ | _____ | _____ | _____ |

Previous month IQC

| | Mean | SD | CV | Z Score |
|-----------|-------|-------|-------|---------|
| Level-I | _____ | _____ | _____ | _____ |
| Level-II | _____ | _____ | _____ | _____ |
| Level-III | _____ | _____ | _____ | _____ |

Previous three month EQAS reports

| | Z score | BIAS | RMZ |
|-----------|---------|-------|-------|
| Month-I | _____ | _____ | _____ |
| Month-II | _____ | _____ | _____ |
| Month-III | _____ | _____ | _____ |

Calibration:

- Was the last calibration acceptable?
- Was the last calibration within the manufacturer's recommended dating?

| YES | NO | NA |
|-------------------------------------|--------------------------|--------------------------|
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Reagent:

| | | | |
|--|----------------|-------------------------|--------------|
| Issued by : Vinod Lonkar <i>Vinod</i> | | Issue Date : 01.09.2023 | |
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| Doc No. GEN 03 | Version No : 1 | Amend No. -- | Amend Date . |

Reagent lot / exp. 4102305 Oct 2024
Lot Expiration

- Was the test reagent stored correctly?
- Was the test reagent properly prepared?
- Was the test reagent within manufacturer's dating?

| YES | NO | NA |
|-------------------------------------|--------------------------|--------------------------|
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Instrument:

- Was daily maintenance performed on the day that the EQAS sample was run?
- Was the person performing maintenance current on training?
- Was the instrument operating correctly on the day the sample was tested?
- Was the lab environment acceptable for the instrument (temperature, humidity, electrical, etc.)?

| YES | NO | NA |
|-------------------------------------|--------------------------|--------------------------|
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Sample Retest:

Sample Send for ILC
Jalandhar.

Who retested sample? Kandhan Date tested _____

- Was the EQAS sample retested following receipt of EQAS sample report?
- If yes, was the result within acceptable limits for the EQAS sample?

| YES | NO | NA |
|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

EQAS Evaluation:

- Inappropriate peer group or comparator?
- Inappropriate evaluation criteria, e.g. narrow limits due to use of a precise method or instrument.

| YES | NO | NA |
|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| | | | |
|--|----------------|-------------------------|--------------|
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Krsnaa Diagnostics Ltd
SDH, Civil Hospital,
Hoshiarpur Road, 3
Dasuva (PR) - 144705

SOP

- Was the SOP followed correctly?

| YES | NO | NA |
|-------------------------------------|--------------------------|--------------------------|
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Staining performed and interpreted correctly?

YES NO NA

Interpretation of microscopic examination interpreted correctly?

YES NO NA

Lot Verification

Type of error Identified - *Temperature out Recieved*
Root cause of the problem

Result out because sample of EQAS Recieved out of Temperature.

Corrective Action

ILC done from Jalandhar Lab.

Signature and Name of Technologist / Section Head

Janchan Devi

Review by QM / HO / TM: Sign and Name

Mr. Balwinder Singh *Balu*

| | | | |
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Metropolis Healthcare Ltd., EQAS
PT Outlier Investigation Report

Lab : 1044 / KRSNAA DIAGNOSTICS LTD DASUYA

Cycle + Sample No : 24010402

Analyte Scheme : Immunoassay Extended

PT Result Received Date : 29/06/2024
 Name Of The Test : Widal test - ParaTyphi A-H antigen (AH)
 Result : 1:160
 Z Score : -

Upload Date : 24/07/2024

Previous trends/Unacceptable results :

last 6-12 month : No Trends
 Last 3 months : No Trends
 Data Entry Check : Yes Data entry is correct
 Investigation : ilc done because sample out of temperature
 Conclusion : Manual method agglutination not proper visible
 Was patient data affected? : Patients Reports are not affected
 Classification Of Problem : Problem with PT material
 Immediate Action : ilc done
 Corrective Action : ilc done
 Preventive Action : review sample temp
 Remark : EQAS sample temp out thats why widal outlier

PT Result Received Date : 29/06/2024
 Name Of The Test : Widal test - ParaTyphi B-H antigen (BH)
 Result : 1:80
 Z Score : -

Upload Date : 24/07/2024

Previous trends/Unacceptable results :

last 6-12 month : No Trends
 Last 3 months : No Trends
 Data Entry Check : Data entry is ok
 Investigation : ilc done because sample out of temp
 Conclusion : manual method agglitination not proper visible
 Was patient data affected? : Patient Reports not effected
 Classification Of Problem : Problem with PT material
 Immediate Action : ilc done
 Corrective Action : ilc done
 Preventive Action : review sample temp
 Remark : EQAS sample temp out thats why widal outlier

Lab : 1044 / KRSNAA DIAGNOSTICS LTD DASUYA

Cycle + Sample No : 24010402

Analyte Scheme : Immunoassay Extended

PT Result Received Date : 29/06/2024
 Name Of The Test : Widal test - ParaTyphi A-H antigen (AH)
 Result : 1:160
 Z Score : -

Upload Date : 24/07/2024

Previous trends/Unacceptable results :

last 6-12 month : No Trends
 Last 3 months : No Trends
 Data Entry Check : Yes Data entry is correct
 Investigation : ilc done because sample out of temperature
 Conclusion : Manual method agglutination not proper visible
 Was patient data affected? : Patients Reports are not affected
 Classification Of Problem : Problem with PT material
 Immediate Action : ilc done
 Corrective Action : ilc done
 Preventive Action : review sample temp
 Remark : EQAS sample temp out thats why widal outlier

PT Result Received Date : 29/06/2024
 Name Of The Test : Widal test - ParaTyphi B-H antigen (BH)
 Result : 1:80
 Z Score : -


Upload Date : 24/07/2024

Previous trends/Unacceptable results :

last 6-12 month : No Trends
 Last 3 months : No Trends
 Data Entry Check : Data entry is ok
 Investigation : ilc done because sample out of temp
 Conclusion : manual method agglutination not proper visible
 Was patient data affected? : Patient Reports not effected
 Classification Of Problem : Problem with PT material
 Immediate Action : ilc done
 Corrective Action : ilc done
 Preventive Action : review sample temp
 Remark : EQAS sample temp out thats why widal outlier

Medical Laboratory Report

Patient Name : Ms RAJNI-BALA
Age and Gender : 25 Years / Female
Category : OPD - PB DASUYA
Referring Doctor : Self
Sample Processed at : PB DASUYA

Patient UID No : DASUY240800015941
PRN No : DASUY240800015941
Registered On : 08 Aug 2024 10:34
Sample UID No. 
119406943

SEROLOGY

| Test Done | Observed Value | Units | Biological Reference Interv |
|---|----------------------------|-------|-----------------------------|
| WIDAL TEST | | | |
| Salmonella typhi O DAGGLUTINATION | 1 : 160 Agglutination seen | | No Agglutination seen |
| Salmonella typhi H DAGGLUTINATION | 1 : 160 Agglutination seen | | No Agglutination seen |
| Salmonella Paratyphi AH DAGGLUTINATION | 1:40 Agglutination seen. | | No Agglutination seen |
| Salmonella Paratyphi BH DAGGLUTINATION | 1:20 Agglutination seen. | | No Agglutination seen |
| Impression DAGGLUTINATION | POSITIVE | | |

Single positive titre should be interpreted with caution. It is advisable to repeat all positive results and look for increasing or decreasing titre levels.
All positive titres are confirmed by tube method.

--- END OF REPORT ---

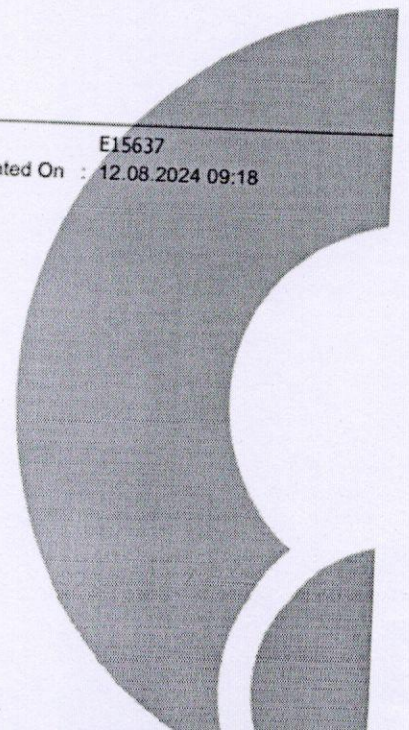


Yasmeen
DR. YASMEEN SINGH
(CONSULTANT PATHOLOGIST)

Sample Collected On : 08.08.2024 10:34
Results Authenticated : 08.08.2024 11:28

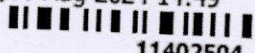
Sample Accepted On : 08.08.2024 10:36
Results Reported : 08.08.2024 11:31

E15637
Printed On : 12.08.2024 09:18



Medical Laboratory Report

Patient Name : Ms RAJNI-BALA
Age and Gender : 25 Years / Female
Category : OPD - PB DASUYA
Referring Doctor : Self
Sample Processed at : KDMPLCHPBJALANDHAR144001

Patient UID No : DASUY240800015941
PRN No : DASUY240800015941
Registered On : 08 Aug 2024 14:49
Sample UID No. 
11402504

SEROLOGY

| Test Done | Observed Value | Units | Biological Reference Interv: |
|---|----------------------------|-------|------------------------------|
| WIDAL TEST | | | |
| Salmonella typhi O Slide Agglutination | 1 : 160 Agglutination seen | | No Agglutination seen |
| Salmonella typhi H Slide Agglutination | 1 : 160 Agglutination seen | | No Agglutination seen |
| Salmonella Paratyphi AH Slide Agglutination | 1:40 Agglutination seen | | No Agglutination seen |
| Salmonella Paratyphi BH Slide Agglutination | 1 : 20 Agglutination seen | | No Agglutination seen |
| Impression | POSITIVE | | |

Single positive titre should be interpreted with caution. It is advisable to repeat all positive results and look for increasing or decreasing titre levels.
All positive titres are confirmed by tube method.



Yasmeen

DR. YASMEEN SINGH
(CONSULTANT PATHOLOGIST)

--- END OF REPORT ---

Sample Collected On : 08.08.2024 14:50
Results Authenticated : 09.08.2024 11:51

Sample Accepted On : 09.08.2024 11:50
Results Reported : 09.08.2024 12:02

E18141
Printed On : 12.08.2024 09:17