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UK NEQAS for Myositis Associated Antibodies

| | | |
|--------------------|--------------|---------------------|
| Distribution : 225 | October 2022 | Participant : 14489 |
|--------------------|--------------|---------------------|

196 out of 226 participants returned data for this distribution. 87% response rate.

Nil Responses

10707, 12257, 13923, 14019, 14513, 14513B, 14599, 14805C, 14873, 90901, 91666, 91754, 95373, 95406, 95767, 96661, 96957, PMS_NZ, PMS_AU, SEROBAC, YVSOLAB, SC_GP, QUAL, ANAND, ORG, BIOG, INFO, CODEX, SEQC, VAR

Sample 225-1 was a plasmapheresis sample from a single donor with no known myositis disease.

Sample 225-2 was a plasmapheresis sample from a single donor with no known myositis disease.

| Sample | Antibody | Designated Response | Your Response | Score |
|--------|-------------------------------------|---------------------|---------------|-------|
| 225-1 | Jo-1 | Negative | Negative | 0 |
| | PL7 | Negative | Negative | 0 |
| | PL12 | Negative | Negative | 0 |
| | PM-SCL100 | Negative | Negative | 0 |
| | Mi-2 | Negative | Negative | 0 |
| | SRP | Negative | Negative | 0 |
| | Other | Negative | Negative | N/A |
| | ANA (nuclear, cytoplasmic, mitotic) | Negative | Negative | N/A |

| Sample | Antibody | Designated Response | Your Response | Score | OMIS |
|--------|-------------------------------------|---------------------|---------------|------------------|---|
| 225-2 | Jo-1 | Negative | Negative | 0 | 0 ● |
| | PL7 | Negative | Negative | 0 | 0 ● |
| | PL12 | Negative | Negative | 0 | 0 ● |
| | PM-SCL100 | Negative | Negative | 0 | 0 ● |
| | Mi-2 | Negative | Negative | 0 | 0 ● |
| | SRP | Negative | Negative | 0 | 1 ● |
| | Other | Negative | Negative | N/A | N/A |
| | ANA (nuclear, cytoplasmic, mitotic) | Negative | Negative | N/A | N/A |
| | | | | Total MIS | 1 ● |

The current window of analysis comprises the previous six distribution

Comments

Sample 225-2 was identical to samples 216-1 and 216-2 .

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Sheffield Teaching Hospitals 
NHS Foundation Trust

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The scoring procedure for the UK NEQAS Myositis Associated Antibodies Scheme is currently within its pilot phase and will be closely monitored and reviewed.

The Total Misclassification scoring (**MIS**) system for the **qualitative** element of the scheme gives an indication of the number of instances where a laboratory's response is at variance with that defined for each specimen in a window of **six** distributions.

A panel of reference laboratories (10656, 10745, 14107, 14131, 23008) were in agreement in providing the target responses.

Laboratories have been given a misclassification score (MIS) for each sample where they are at variance with the target response. The overall misclassification score (OMIS) now includes a running window of 12 samples over 12 months.

The categories of performance are:

| | | Total MIS |
|--|---|-----------|
|  Good | - | zero |
|  Adequate | - | 1 - 3 |
|  Poor | - | > 3 |

For further performance criteria information please see our website at <http://www.immqas.org.uk>.

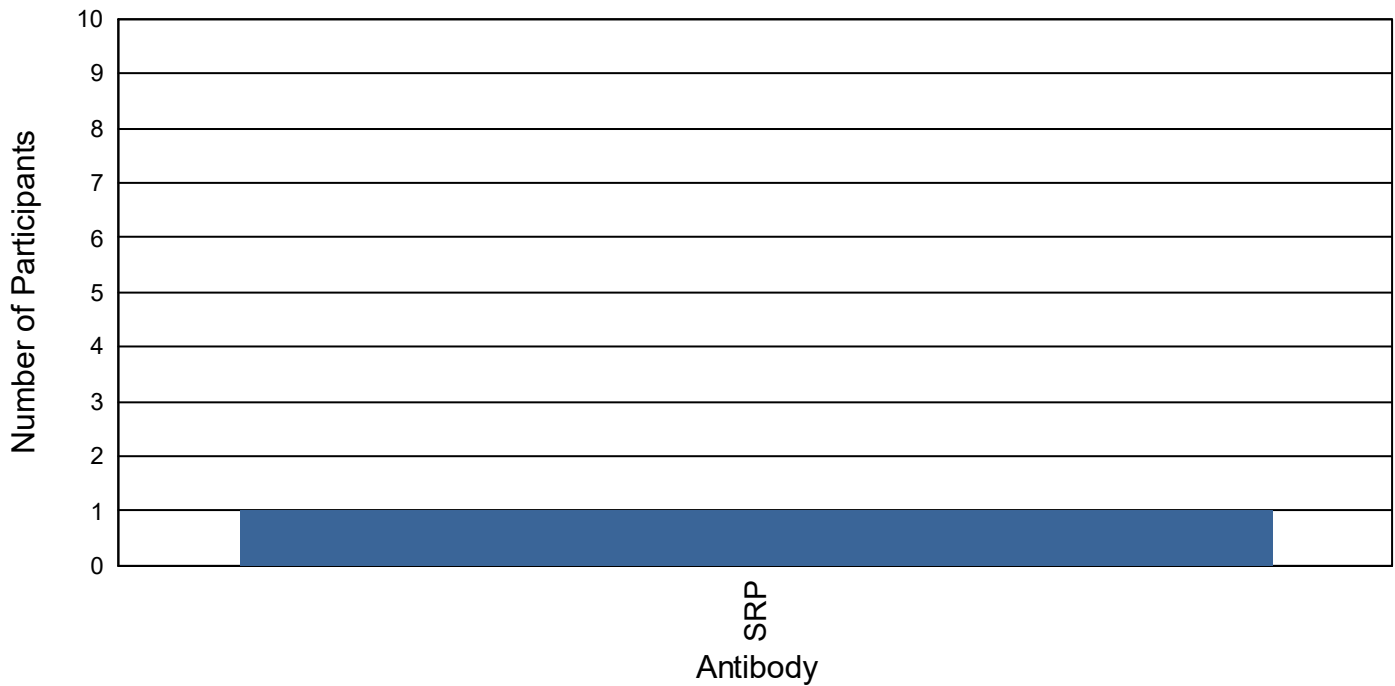
If laboratories require further assistance please contact the centre.

Summary Page for Sample 225-1

| Myositis Associated Antibodies | Present | Absent |
|--------------------------------|---------|--------|
| | 3 | 150 |

| Antibody | Returns | Positive | Negative |
|-----------|---------|----------|----------|
| Jo-1 | 192 | 0 | 192 |
| PL7 | 186 | 0 | 186 |
| PL12 | 186 | 0 | 186 |
| PM-SCL100 | 183 | 0 | 183 |
| Mi-2 | 189 | 0 | 189 |
| SRP | 185 | 1 | 184 |
| Other | 143 | 0 | 143 |
| ANA | 167 | 16 | 151 |

Positive Responses



Your Results for Sample 225-1

Jo-1: Negative

Jo-1 Method: Immunoblotting/Immunodot

Jo-1 Manufacturer: Euroimmun Myositis Profile 3

PM-SCL100: Negative

PM-SCL 100 Method: Immunoblotting/Immunodot

PM-SCL100 Manufacturer: Euroimmun Myositis Profile 3

Other: Negative

Other Method: No Response

Other Manufacturer: No Response

Software used EUROLineScan

PL7: Negative

PL7 Method: Immunoblotting/Immunodot

PL7 Manufacturer: Euroimmun Myositis Profile 3

Mi-2: Negative

Mi-2 Method: Immunoblotting/Immunodot

Mi-2 Manufacturer: Euroimmun Myositis Profile 3

PL12: Negative

PL12 Method: Immunoblotting/Immunodot

PL12 Manufacturer: Euroimmun Myositis Profile 3

SRP: Negative

SRP Method: Immunoblotting/Immunodot

SRP Manufacturer: Euroimmun Myositis Profile 3

| | Jo-1 | | PL7 | | PL12 | | PM-SCL100 | | Mi-2 | | SRP | | Other | |
|--------------------------------------|----------|------------|----------|------------|----------|------------|-----------|------------|----------|------------|----------|------------|----------|------------|
| | POS | NEG | POS | NEG | POS | NEG | POS | NEG | POS | NEG | POS | NEG | POS | NEG |
| Enzyme Immunoassay/ELISA | 0 | 9 | 0 | 1 | 0 | 1 | 0 | 12 | 0 | 6 | 0 | 1 | 0 | 1 |
| Other ... | 0 | 3 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 1 |
| Phadia 250 EliA | 0 | 6 | 0 | 0 | 0 | 0 | 0 | 11 | 0 | 5 | 0 | 0 | 0 | 0 |
| Immunoblotting/Immunodot | 0 | 178 | 0 | 182 | 0 | 181 | 0 | 168 | 0 | 178 | 1 | 181 | 0 | 136 |
| A. Menarini - Zenit Amidot | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 0 |
| Alpha Dia Myositis Profile 10 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 2 |
| Alpha Dia Myositis Profile 12 | 0 | 18 | 0 | 19 | 0 | 17 | 0 | 8 | 0 | 22 | 0 | 21 | 0 | 14 |
| Alpha Dia Myositis Profile 9 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Alpha Dia Synthetase Profile 10 | 0 | 4 | 0 | 4 | 0 | 4 | 0 | 3 | 0 | 0 | 0 | 2 | 0 | 1 |
| D-Tek MYO 12 | 0 | 5 | 0 | 6 | 0 | 5 | 0 | 4 | 0 | 5 | 0 | 6 | 0 | 5 |
| D-Tek MYO 7D-24 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 2 | 0 | 1 | 0 | 1 |
| D-Tek MYOS 12DIV | 0 | 3 | 0 | 1 | 0 | 3 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 1 |
| D-Tek MYOS12D-24 | 0 | 5 | 0 | 6 | 0 | 5 | 0 | 2 | 0 | 5 | 0 | 6 | 0 | 5 |
| D-Tek PMS12D-24 | 0 | 6 | 0 | 6 | 0 | 6 | 0 | 6 | 0 | 6 | 0 | 6 | 0 | 4 |
| Euroimmun Myositis Profile | 0 | 3 | 0 | 2 | 0 | 3 | 0 | 2 | 0 | 3 | 0 | 2 | 0 | 11 |
| Euroimmun Myositis Profile 16 | 0 | 99 | 0 | 102 | 0 | 101 | 0 | 99 | 0 | 99 | 1 | 100 | 0 | 70 |
| Euroimmun Myositis Profile 3 | 0 | 14 | 0 | 14 | 0 | 15 | 0 | 15 | 0 | 15 | 0 | 14 | 0 | 11 |
| Euroimmun Myositis Profile 4 | 0 | 11 | 0 | 12 | 0 | 10 | 0 | 13 | 0 | 9 | 0 | 12 | 0 | 7 |
| Euroimmun Myositis Profile 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| Euroimmun Syst. Sclerosis Profile | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 0 | 0 | 0 |
| Generic Assays Dot Diver Myositis 10 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 0 |
| ORGenTec Myositis Plus | 0 | 4 | 0 | 4 | 0 | 4 | 0 | 4 | 0 | 4 | 0 | 4 | 0 | 1 |
| Other ... | 0 | 3 | 0 | 3 | 0 | 3 | 0 | 5 | 0 | 3 | 0 | 4 | 0 | 3 |
| Other ... | 0 | 2 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 1 |
| Other ... | 0 | 2 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 1 |

No Positive results returned for Other for this Sample

| | Qualitative | Quantitative | Unit | Method | Manufacturer |
|----------------|-------------|--------------|-------|-----------------------------|--------------|
| Your Response: | Negative | None | Titre | Indirect Immunofluorescence | Euroimmun |

| Pattern Source | Pattern Category (ICAP) | Count |
|----------------|------------------------------------|-------|
| Nuclear | Discrete nuclear dots (AC-6, AC-7) | 3 |
| Nuclear | Nucleolar (AC-8, AC-9, AC-10) | 2 |
| Nuclear | Pleomorphic (AC-13, AC-14) | 1 |
| Nuclear | Speckled (AC-2, AC-4, AC-5, AC-29) | 2 |
| Nuclear | Multiple nuclear dots (AC-6) | 3 |
| Nuclear | PCNA-like (AC-13) | 1 |
| Cytoplasmic | Reticular / AMA (AC-21) | 2 |
| Cytoplasmic | Speckled (AC-18, AC-19, AC-20) | 15 |
| Cytoplasmic | Discrete dots (AC-18) | 1 |
| Cytoplasmic | Dense fine speckled (AC-19) | 6 |
| Cytoplasmic | Fine speckled (AC-20) | 3 |
| Negative | Negative (AC-0) | 131 |

| | Returns | Positive | Negative | Mean | Observed Range |
|------------------------------------|------------|-----------|------------|------------|----------------|
| Indirect Immunofluorescence | 161 | 16 | 145 | 170 | 0 640 |
| HEp-2 | 147 | 13 | 134 | 157 | 0 640 |
| A. Menarini - Zenit EIA | 3 | 0 | 3 | 80 | 80 80 |
| AESKU | 10 | 1 | 9 | 200 | 80 320 |
| BioDiagnostics | 1 | 1 | 0 | 640 | 640 640 |
| Bio-Rad/Kallestad/Sanofi | 11 | 8 | 3 | 503 | 160 1280 |
| Biosystems | 2 | 0 | 2 | 0 | 0 0 |
| Euroimmun | 42 | 0 | 42 | 50 | 0 80 |
| Immunoconcepts | 8 | 0 | 8 | 80 | 80 80 |
| Inova | 66 | 3 | 63 | 80 | 0 160 |
| Other ... | 2 | 0 | 2 | 80 | 80 80 |
| Trinity Biotech (Immco) | 1 | 0 | 1 | 0 | 0 0 |
| ZEUS | 1 | 0 | 1 | 0 | 0 0 |
| HEp-2000 | 13 | 3 | 10 | 280 | 160 400 |
| Immunoconcepts | 13 | 3 | 10 | 280 | 160 400 |
| Other ... | 1 | 0 | 1 | 320 | 320 320 |
| Euroimmun | 1 | 0 | 1 | 320 | 320 320 |

Please note: The statistical figures in the tables above are trimmed

| | Returns | Positive | Negative | Mean | Observed Range | |
|--------------------------------------|----------|----------|----------|----------|----------------|----------|
| Luminex Technology | 1 | 0 | 1 | 0 | 0 | 0 |
| Index | | | | | | |
| Luminex Tech. - Bio-Rad Bioplex 2200 | 1 | 0 | 1 | 0 | 0 | 0 |
| Enzyme Immunoassay/ELISA | 5 | 0 | 5 | 1 | 0 | 1 |
| IU/ml | | | | | | |
| Inova | 2 | 0 | 2 | 1 | 0 | 1 |
| Ratio | | | | | | |
| Phadia 250 EIIA | 1 | 0 | 1 | 0 | 0 | 0 |
| Phadia 250 EIIA (CTD) | 2 | 0 | 2 | 0 | 0 | 0 |

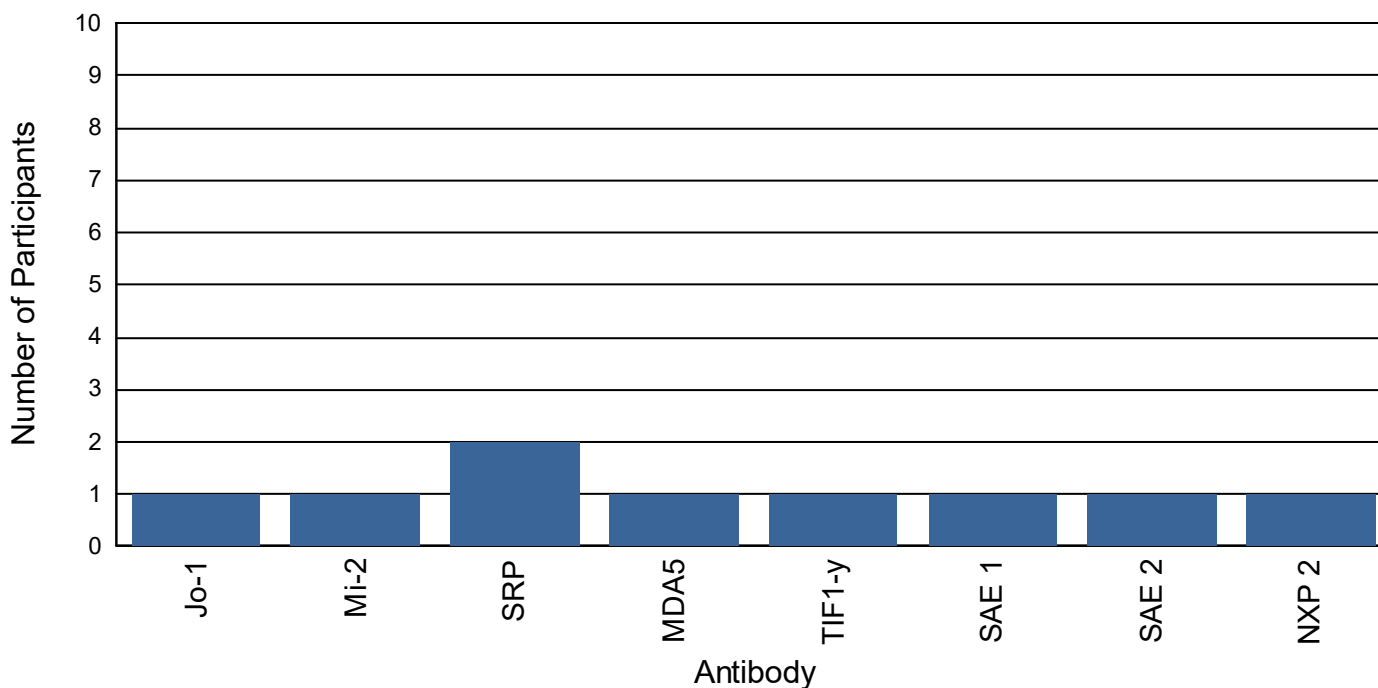
Please note: The statistical figures in the tables above are trimmed

Summary Page for Sample 225-2

| Myositis Associated Antibodies | Present | Absent |
|--------------------------------|---------|--------|
| | 1 | 144 |

| Antibody | Returns | Positive | Negative |
|-----------|---------|----------|----------|
| Jo-1 | 193 | 1 | 192 |
| PL7 | 187 | 0 | 187 |
| PL12 | 188 | 0 | 188 |
| PM-SCL100 | 183 | 0 | 183 |
| Mi-2 | 190 | 1 | 189 |
| SRP | 186 | 2 | 184 |
| Other | 145 | 1 | 144 |
| MDA5 | 1 | 1 | |
| TIF1-y | 1 | 1 | |
| SAE 1 | 1 | 1 | |
| SAE 2 | 1 | 1 | |
| NXP 2 | 1 | 1 | |
| ANA | 168 | 1 | 167 |

Positive Responses



Your Results for Sample 225-2

Jo-1: Negative

Jo-1 Method: Immunoblotting/Immunodot

Jo-1 Manufacturer: Euroimmun Myositis Profile 3

PM-SCL100: Negative

PM-SCL 100 Method: Immunoblotting/Immunodot

PM-SCL100 Manufacturer: Euroimmun Myositis Profile 3

Other: Negative

Other Method: No Response

Other Manufacturer: No Response

Software used EUROLineScan

PL7: Negative

PL7 Method: Immunoblotting/Immunodot

PL7 Manufacturer: Euroimmun Myositis Profile 3

Mi-2: Negative

Mi-2 Method: Immunoblotting/Immunodot

Mi-2 Manufacturer: Euroimmun Myositis Profile 3

PL12: Negative

PL12 Method: Immunoblotting/Immunodot

PL12 Manufacturer: Euroimmun Myositis Profile 3

SRP: Negative

SRP Method: Immunoblotting/Immunodot

SRP Manufacturer: Euroimmun Myositis Profile 3

| | Jo-1 | | PL7 | | PL12 | | PM-SCL100 | | Mi-2 | | SRP | | Other | |
|--------------------------------------|----------|------------|----------|------------|----------|------------|-----------|------------|----------|------------|----------|------------|----------|------------|
| | POS | NEG | POS | NEG | POS | NEG | POS | NEG | POS | NEG | POS | NEG | POS | NEG |
| Enzyme Immunoassay/ELISA | 1 | 8 | 0 | 1 | 0 | 1 | 0 | 11 | 0 | 6 | 0 | 1 | 0 | 1 |
| Other ... | 0 | 3 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 1 |
| Phadia 250 EliA | 1 | 5 | 0 | 0 | 0 | 0 | 0 | 10 | 0 | 5 | 0 | 0 | 0 | 0 |
| Immunoblotting/Immunodot | 0 | 179 | 0 | 183 | 0 | 182 | 0 | 169 | 1 | 178 | 2 | 181 | 1 | 137 |
| A. Menarini - Zenit Amidot | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 0 |
| Alpha Dia Myositis Profile 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 2 |
| Alpha Dia Myositis Profile 12 | 0 | 18 | 0 | 19 | 0 | 18 | 0 | 8 | 1 | 21 | 1 | 20 | 1 | 13 |
| Alpha Dia Myositis Profile 9 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Alpha Dia Synthetase Profile 10 | 0 | 4 | 0 | 4 | 0 | 4 | 0 | 3 | 0 | 0 | 0 | 2 | 0 | 1 |
| D-Tek MYO 12 | 0 | 5 | 0 | 6 | 0 | 5 | 0 | 4 | 0 | 5 | 0 | 6 | 0 | 5 |
| D-Tek MYO 7D-24 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 2 | 0 | 1 | 0 | 1 |
| D-Tek MYOS 12DIV | 0 | 3 | 0 | 1 | 0 | 3 | 0 | 0 | 0 | 3 | 0 | 1 | 0 | 1 |
| D-Tek MYOS12D-24 | 0 | 5 | 0 | 6 | 0 | 5 | 0 | 2 | 0 | 5 | 0 | 6 | 0 | 5 |
| D-Tek PMS12D-24 | 0 | 6 | 0 | 6 | 0 | 6 | 0 | 6 | 0 | 6 | 0 | 6 | 0 | 4 |
| Euroimmun Myositis Profile | 0 | 3 | 0 | 2 | 0 | 3 | 0 | 2 | 0 | 3 | 0 | 2 | 0 | 11 |
| Euroimmun Myositis Profile 16 | 0 | 100 | 0 | 103 | 0 | 103 | 0 | 101 | 0 | 101 | 1 | 101 | 0 | 73 |
| Euroimmun Myositis Profile 3 | 0 | 14 | 0 | 14 | 0 | 14 | 0 | 14 | 0 | 14 | 0 | 13 | 0 | 10 |
| Euroimmun Myositis Profile 4 | 0 | 11 | 0 | 12 | 0 | 10 | 0 | 13 | 0 | 9 | 0 | 12 | 0 | 7 |
| Euroimmun Myositis Profile 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| Euroimmun Syst. Sclerosis Profile | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 0 | 0 | 0 |
| Generic Assays Dot Diver Myositis 10 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 0 |
| ORGenTec Myositis Plus | 0 | 4 | 0 | 4 | 0 | 4 | 0 | 4 | 0 | 4 | 0 | 4 | 0 | 1 |
| Other ... | 0 | 3 | 0 | 3 | 0 | 3 | 0 | 5 | 0 | 3 | 0 | 4 | 0 | 3 |
| Other ... | 0 | 2 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 1 |
| Other ... | 0 | 2 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 1 |

| | PM-SCL75 | PM-SCL | Ro-52 | AMA-M2 | Ku | Ku (p70/80) | Mi-2 Alpha | Mi-2 Beta | U1-snRNP | Rib-P | OJ | EJ | MDA5 | TIF1-y | HMGCR | SAE 1 | SAE 2 | NXP 2 | Other |
|---------------------------------|----------|----------|----------|----------|----------|-------------|------------|-----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| | POS | POS | POS | POS | POS | POS | POS | POS | POS | POS | POS | POS | POS | POS | POS | POS | POS | POS | POS |
| Immunoblotting/Immunodot | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 1 | 1 | 1 | 0 |
| Alpha Dia Myositis Profile 12 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 1 | 1 | 1 | 0 |

| | Qualitative | Quantitative | Unit | Method | Manufacturer |
|----------------|-------------|--------------|-------|-----------------------------|--------------|
| Your Response: | Negative | None | Titre | Indirect Immunofluorescence | Euroimmun |

| Pattern Source | Pattern Category (ICAP) | Count |
|----------------|------------------------------------|-------|
| Nuclear | Speckled (AC-2, AC-4, AC-5, AC-29) | 1 |
| Nuclear | Dense fine speckled (AC-2) | 1 |
| Negative | Negative (AC-0) | 147 |

| | Returns | Positive | Negative | Mean | Observed Range |
|------------------------------------|------------|----------|------------|------------|----------------|
| Indirect Immunofluorescence | 161 | 1 | 160 | 73 | 0 160 |
| HEp-2 | 146 | 1 | 145 | 67 | 0 80 |
| A. Menarini - Zenit EIA | 3 | 0 | 3 | 80 | 80 80 |
| AESKU | 10 | 0 | 10 | 80 | 80 80 |
| BioDiagnostics | 1 | 0 | 1 | 80 | 80 80 |
| Bio-Rad/Kallestad/Sanofi | 11 | 0 | 11 | 0 | 0 0 |
| Biosystems | 2 | 0 | 2 | 0 | 0 0 |
| Euroimmun | 43 | 0 | 43 | 80 | 80 80 |
| Immunoconcepts | 7 | 0 | 7 | 80 | 80 80 |
| Inova | 65 | 1 | 64 | 93 | 0 160 |
| Other ... | 2 | 0 | 2 | 80 | 80 80 |
| Trinity Biotech (Immco) | 1 | 0 | 1 | 0 | 0 0 |
| ZEUS | 1 | 0 | 1 | 0 | 0 0 |
| HEp-2000 | 14 | 0 | 14 | 0 | 0 0 |
| Immunoconcepts | 14 | 0 | 14 | 0 | 0 0 |
| Other ... | 1 | 0 | 1 | 320 | 320 320 |
| Euroimmun | 1 | 0 | 1 | 320 | 320 320 |

Please note: The statistical figures in the tables above are trimmed

| | Returns | Positive | Negative | Mean | Observed Range | |
|--------------------------------------|----------|----------|----------|----------|----------------|----------|
| Luminex Technology | 1 | 0 | 1 | 0 | 0 | 0 |
| Index | | | | | | |
| Luminex Tech. - Bio-Rad Bioplex 2200 | 1 | 0 | 1 | 0 | 0 | 0 |
| Enzyme Immunoassay/ELISA | 5 | 0 | 5 | 2 | 2 | 2 |
| IU/ml | | | | | | |
| Inova | 2 | 0 | 2 | 2 | 2 | 2 |
| Ratio | | | | | | |
| Phadia 250 EIIA | 1 | 0 | 1 | 0 | 0 | 0 |
| Phadia 250 EIIA (CTD) | 2 | 0 | 2 | 0 | 0 | 0 |

Please note: The statistical figures in the tables above are trimmed