Standardised Reporting of Protein Electrophoresis

Pavai
University Malaya
Protein electrophoresis

• Primary role is to detect monoclonal immunoglobulins associated with plasma cell dyscrasias and lymphoproliferative disorders

• The most common interpretative report encountered in clinical biochemistry is protein electrophoresis and immunofixation.

• While reports are provided by many laboratories, there are often substantial differences in the content and structure of interpretative comments between individuals and institutions
SPEP report - What do clinicians want?

• Is there a monoclonal protein?

• What is the isotype and concentration?

• Cumulative reporting – to calculate the response to the therapy/ to monitor the progression of disease or relapse

• Consistent reporting of monoclonal proteins

• Uniform approach to report monoclonal proteins which migrate with normal serum proteins

• Recognition and reporting of oligoclonal and small bands that occur post BM transplant or novel therapy
• There is a considerable progress that has been made in the diagnostic criteria, diagnostic workup, prognosis, and treatment of patients with multiple myeloma

• **But in terms of reporting there are only very few guidelines available for standardized reporting**

• There is a wide variation in current practice suggests that it will be a long road to reporting standardisation

• Variation in reporting can cause confusion for the clinician with potential to adversely impact patient care
What are the areas with significant inter-laboratory variation?

• Quantification of co-migrating monoclonal proteins in the beta/alpha region

• Quantification/reporting of small bands

• Report formats/comments?

• Nomenclature and units

• Others???
What are the reasons for inter-lab variation?

- Different analytical methods – eg: Capillary Vs Gel, ISUB Vs IFE

- Different techniques of monoclonal protein quantification – Perpendicular/ tangent skimming/ corrected perpendicular

- Different report formats - ? due to LIS limitations/ clinician preferences/ ?? historical – don’t want to change

- Others??
Potential benefits of standardised reporting

A uniform reporting practice has the potential to promote consistency and...

• compliance with consensus guidelines
• reduce the possibility of misinterpretation by clinician
• comparability of serial reports through standard format and terminology
• reduce typographical errors

reduce reporting time, by facilitating:

• review of previous reports
• uniform construction of interpretative comments
• improve precision by harmonising the use of semi-quantitative terms
• facilitate medical peer review and research activities
Recommendations and guidelines

• The first set of guidelines: Guidelines for Clinical and Laboratory Evaluation of Patients With Monoclonal Gammopathies –approved by CAP in 1999

• Revised and updated in 2012 to reflect the advances in the analysis of protein electrophoresis

• Italian biochemistry and molecular genetics published recommendations in Italian and the Netherlands published national recommendations in Dutch, which have limited utility outside the country of origin.

• Standardised reporting of protein electrophoresis are from Australia and New Zealand- 2012

• Moving towards harmonised reporting of serum and urine protein electrophoresis IFCC opinion paper 2016

• Candidate recommendations for protein electrophoresis reporting from the Canadian Society of Clinical Chemists Monoclonal Gammopathy Working Group- 2018
Candidate recommendations for protein electrophoresis reporting from the Canadian Society of Clinical Chemists Monoclonal Gammopathy Working Group

Opinion Paper

Michael A. Moss*

Moving towards harmonized reporting of serum and urine protein electrophoresis

Recommendations for standardized reporting of protein electrophoresis in Australia and New Zealand

Jillian Tate¹, Grahame Caldwell², James Daly³, David Gillis⁴, Margaret Jenkins⁵, Sue Jovanovich⁶, Helen Martin⁷, Richard Steele⁸, Louise Wienholt⁹ and Peter Mollee¹⁰ on behalf of the Working Party on Standardised Reporting of Protein Electrophoresis

Screening and Diagnosis of Monoclonal Gammopathies

An International Survey of Laboratory Practice

Jonathan R. Genzen, MD, PhD; David L. Murray, MD, PhD; Gyorgy Abel, MD, PhD; Qing H. Meng, MD, PhD; Richard J. Balsamo, MD; Daniel D. Rhoads, MD; Julio C. Delgado, MD; Rhona J. Soyers, MS; Christine Basileben, MT(ASCP); David F. Keren, MD; Mohammad Q. Ansai, MD
Are there any laboratory guidelines/recommendations in Aus & NZ?

Recommendations for standardized reporting of protein electrophoresis in Australia and New Zealand

Jillian Tate¹, Grahame Caldwell², James Daly³, David Gillis⁴, Margaret Jenkins⁵, Sue Jovanovich⁶, Helen Martin⁷, Richard Steele⁸, Louise Wienenholt⁹ and Peter Mollee¹⁰ on behalf of the Working Party on Standardised Reporting of Protein Electrophoresis

¹Chemical Pathology Department, Pathology Queensland, Royal Brisbane and Women’s Hospital, Herston Road, Brisbane, Queensland 4029; ²Douglas Harry Moir Pathology, Macquarie Park, New South Wales; ³Haematology Department, Royal Hobart Hospital, Hobart, Tasmania; ⁴Immunology Department, Pathology Queensland, Royal Brisbane and Women’s Hospital, Brisbane, Queensland; ⁵Biochemistry Department, Austin Hospital, Heidelberg, Victoria; ⁶RCPA Immunology QAP, SA Pathology, Flinders Medical Centre, Adelaide; ⁷Biochemistry Department, Healthscope Pathology, Wayville, South Australia, Australia; ⁸Immunology Department, Wellington Hospital, Wellington, New Zealand; ⁹Clinical Immunology, Royal Prince Alfred Hospital, Sydney, New South Wales; ¹⁰Haematology Department, Pathology Queensland, Princess Alexandra Hospital, Ipswich, Queensland, Australia

Corresponding author: Jillian Tate. Email: jill.tate@health.qld.gov.au


• Recommendations for
  - Nomenclature
  - Detection systems
  - Serum protein and albumin quantification
  - Quantitative reporting of SPEP fractions
  - Quantification small bands and paraproteins co-migrating with other normal proteins in alpha and beta regions
  - Serum and urine paraprotein quantification
  - Paraprotein characterization
  - Laboratory performance of SPEP, UPEP and IFE
  - Laboratory expertise and staffing
  - Report formats
Summary of CSCC MGWG consensus statements.

Information to be included in reports

- Laboratories should report the same quantity of information in the same format
- Reports should be consistent between interpreters
- SPE reports that indicate the presence of a monoclonal immunoglobulin should include its isotype (when previously known), and its concentration
- When confirmation testing (e.g. IFE) is not possible/available, it should be stated that there is an abnormality present and additional testing is recommended

Fraction reporting

- SPE reports should include protein fraction quantitation
- Monoclonal proteins (when present) should be quantitated and reported independent of other fractions
- Protein and monoclonal fractions should be reported in g/L
- Normal protein fractions should be reported with a healthy population-based reference interval

Interferences

- Interpreters should be educated about types of interferences and options to resolve them
- Clinicians receiving reports from samples with interferences should be explicitly informed in the interpretative comments about limitations (e.g. quantitation accuracy, false positive bands)
- Interpreters and clinicians should communicate about consistent approaches to reporting results in patients receiving monoclonal therapies
Nomenclature

• Serum
  • Monoclonal protein – used to describe an unknown monoclonal immunoglobulin prior to immunotyping or when referring nonspecifically to a monoclonal immunoglobulin. The term encompasses monoclonal immunoglobulins, monoclonal free light chains and monoclonal free heavy chains when present in either serum or urine. The recommended abbreviation is M-protein.
  • Monoclonal immunoglobulin – used for whole molecule monoclonal immunoglobulins e.g. monoclonal IgG kappa, monoclonal IgG lambda, monoclonal IgA kappa (etc.). The recommended abbreviation is M-Ig.
  • Monoclonal free light chains
  • Oligoclonal IgG bands refers to two or more bands of gamma mobility on protein electrophoresis. Isoelectric focusing is a useful technique to distinguish monoclonal bands from overlapping oligoclonal bands and polyclonal IgG.

• Urine
  • Bence Jones protein or monoclonal free light chains
  • Intact immunoglobulins
• Fractions to be reported (if reported):
  • Albumin
  • Alpha 1 Globulins
  • Alpha 2 Globulins
  • Beta Globulins (ideally Beta 1 & 2)
  • Gamma Globulins

• When reporting fractions to clinical users, laboratories should include:
  • Appropriate reference intervals
  • Significant digits according to achievable analytical precision
  • When reporting protein fractions, the analytical methodology should be clearly indicated if they are also reported from the same laboratory using other techniques (e.g. Albumin (by SPE) and Albumin)
Hawkins: When the precision (SD) is < 0.7 units, then 1 decimal is appropriate, and SD < 0.07 units, then 2 decimal places are appropriate.

### Calculation of the number of decimals that should be reported using 2 methods.

<table>
<thead>
<tr>
<th>Protein fraction</th>
<th>Mean (g/L)</th>
<th>SD</th>
<th>Hawkins &amp; Johnson method (≤ 0.7)</th>
<th>Reporting decimals</th>
<th>Badrick et al. @ p = 0.5</th>
<th>Badrick et al. @ p = 0.05</th>
<th>Reporting decimals (p = 0.5)</th>
<th>Reporting decimals (p = 0.05)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin</td>
<td>66.6</td>
<td>0.71</td>
<td>FALSE</td>
<td>None</td>
<td>0.677</td>
<td>1.967</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Alpha 1</td>
<td>2.5</td>
<td>0.16</td>
<td>TRUE</td>
<td>1</td>
<td>0.153</td>
<td>0.443</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Alpha 2</td>
<td>9.3</td>
<td>0.22</td>
<td>TRUE</td>
<td>1</td>
<td>0.210</td>
<td>0.609</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>Beta</td>
<td>10.1</td>
<td>0.36</td>
<td>TRUE</td>
<td>1</td>
<td>0.343</td>
<td>0.997</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>Gamma</td>
<td>11.5</td>
<td>0.48</td>
<td>TRUE</td>
<td>1</td>
<td>0.458</td>
<td>1.330</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>Mlg low</td>
<td>5.6</td>
<td>0.17</td>
<td>TRUE</td>
<td>1</td>
<td>0.162</td>
<td>0.471</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Mlg high</td>
<td>32.2</td>
<td>2.00</td>
<td>FALSE</td>
<td>None</td>
<td>1.908</td>
<td>5.540</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>
Analytical technologies

• The system used for quantitative electrophoresis **should be of high resolution** and be able to detect small monoclonal bands that may co-migrate with normal proteins particularly in the beta region.

• The techniques used should be sufficiently sensitive to detect small monoclonal immunoglobulins (< 1 g/L) co-migrating with polyclonal immunoglobulins.
Serum monoclonal protein/ monoclonal protein quantification

• Monoclonal immunoglobulins should be quantitated and reported as discrete results to allow for result trending over time.

• Monoclonal immunoglobulins co-migrating with other protein fractions should be clearly indicated to contain some portion of normal globulins. The laboratory should provide guidance to the clinician as the range of normal globulins present in the co-migrating normal globulin fraction.

• The presence of an abnormal or monoclonal-appearing band upon electrophoresis should prompt further investigation by IFE Immunotyping: Either by IFE or immunosubtraction
  • correct interpretation and characterization of monoclonal immunoglobulins to be more consistent with IFE than immunosubtraction (Canadian guidelines)
  • gel-based method should also be available for low concentration gammopathies and detection of IgD and IgE monoclonal proteins
Protein electrophoresis and response criteria for multiple myeloma

<table>
<thead>
<tr>
<th>Response category</th>
<th>Abbreviation</th>
<th>Response criteria</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete remission</td>
<td>CR</td>
<td>Negative IFE of the serum and urine samples</td>
<td>IFE required if paraprotein not visible on electrophoretogram</td>
</tr>
<tr>
<td>Near complete remission</td>
<td>nCR</td>
<td>Paraprotein visible by IFE but not on electrophoresis of the serum or urine samples</td>
<td>IFE required if paraprotein not visible on electrophoretogram</td>
</tr>
<tr>
<td>Very good partial remission</td>
<td>vgPR</td>
<td>Paraprotein visible by IFE but not on electrophoresis of the serum or urine samples OR &gt;90% reduction in serum paraprotein plus urine paraprotein &lt;100 mg/24 h</td>
<td>IFE required if paraprotein not visible on electrophoretogram</td>
</tr>
<tr>
<td>Partial remission</td>
<td>PR</td>
<td>&gt;50% reduction of serum paraprotein and reduction in 24-h urinary paraprotein by &gt;90% or to &lt;200 mg/24 h</td>
<td>Allow use of quantitative immunoglobulin concentrations in patients in whom the paraprotein measurements are unreliable (e.g. IgA paraproteins co-migrating with the beta region)</td>
</tr>
<tr>
<td>Progressive disease</td>
<td>PD</td>
<td>25% increase from nadir of serum paraprotein (the absolute increase must be ≥5 g/L) OR 25% increase from nadir of urine paraprotein (the absolute increase must be ≥200 mg/24 h)</td>
<td></td>
</tr>
<tr>
<td>Stable disease</td>
<td>SD</td>
<td>Not meeting criteria for CR, vgPR, PR or PD</td>
<td></td>
</tr>
</tbody>
</table>
Quantitation of small monoclonal immunoglobulins & lower limit of reporting

• There is currently no evidence to guide recommendation for a single lower limit of reporting.

• However, an IFCC-sponsored project is currently assessing the functional sensitivity of SPE and immunotyping methods which will provide information on method sensitivity.

• Laboratories should determine the lower limit of reporting based on the analytical performance of the method used in the laboratory.

• Tate et al. previously recommend the lower limit of quantitation be 1 g/L. (Ann Clin Biochem 2012; 49: 242–256)

• Booth et al. 1 G/L (Clinical Biochemistry 2018 51: 10–20)
Small bands after stem cell transplantation

- Small abnormal protein bands are frequently seen on SPEP following transplantation
- Often immunofixation reveals not only oligoclonal bands but small discrete bands with the appearance of a paraprotein
  - Most commonly IgG kappa
  - Typically ≤1 g/L but may occasionally be larger
  - Persist from between one to 18 months
- Likely due to transient dysregulation of the regenerating B cell compartment during haematopoietic recovery
Event-free survival rates

- Abnormal protein band: Event-free survival decreases significantly over time compared to those with no abnormal protein bands.
- The difference is statistically significant with p=0.04.
Serum protein CE electropherograms (Sebia Capillarys) showing three methods of measuring M-protein peaks.

Schild et al. diluted an IgG M-protein and an IgA M-protein in normal serum and measured the M-protein spike by perpendicular drop for IgG (shaded squares) and IgA (shaded triangles) and by the tangent method for IgG (unshaded squares) and for IgA (unshaded triangles). The perpendicular drops were linear to 15 g/L (1.5 g/dL) whereas the tangent measurements were linear to 1.5 g/L (0.15 g/dL).
Reference change value

• When reporting serial protein electrophoresis, interpreters should review previous history and indicate if there is a significant change in monoclonal fraction quantitation.

• Laboratory information systems can provide a delta checking feature which could be used to facilitate recognition of significant changes in monoclonal protein quantitation.
# Handling interferences with SPE/UPE/IFE

<table>
<thead>
<tr>
<th>Interference</th>
<th>Method affected</th>
<th>Action for resolution</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fibrinogen</td>
<td>SPE/IFE (both capillary and agarose gel methods)</td>
<td>Thrombin treatment, ethanol precipitation, pre-absorption of antisera</td>
<td>Common</td>
</tr>
<tr>
<td>Contrast dyes</td>
<td>Capillary electrophoresis</td>
<td>IFE is unaffected</td>
<td>Uncommon</td>
</tr>
<tr>
<td>Antifungal SFC</td>
<td>Capillary electrophoresis</td>
<td>IFE is unaffected</td>
<td>Uncommon</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>SPE (capillary and agarose gel)</td>
<td>IFE is unaffected</td>
<td>Uncommon</td>
</tr>
<tr>
<td>Hemolysis</td>
<td>SPE (capillary and agarose gel)</td>
<td>IFE is unaffected</td>
<td>Common</td>
</tr>
<tr>
<td>Heterophilic antibodies</td>
<td>IFE (capillary and agarose gel)</td>
<td>Clinical awareness/education</td>
<td>Rare</td>
</tr>
<tr>
<td>Polyclonal IgG mimics</td>
<td>IFE (capillary and agarose gel)</td>
<td>Clinical awareness/education</td>
<td>Rare</td>
</tr>
<tr>
<td>Gelatin-based plasma substitutes</td>
<td>SPE (capillary and agarose gel)</td>
<td>IFE is unaffected</td>
<td>Very rare</td>
</tr>
<tr>
<td>Hydroxycobalamin</td>
<td>Capillary electrophoresis</td>
<td>IFE is unaffected</td>
<td>Very rare</td>
</tr>
<tr>
<td>Monoclonal therapies</td>
<td>SPE/UPE/IFE (capillary and agarose gel)</td>
<td>Clinical awareness/education, migration shift assays, mass spectrometry</td>
<td>Rare, but may become significant in the future</td>
</tr>
</tbody>
</table>
Additional pathological patterns

• In addition to identifying monoclonal gammopathies, protein electrophoresis has the ability to identify other protein electrophoretic patterns that are not related to monoclonal gammopathies but are characteristic of other disorders.
Proposed components of a harmonized comment set for serum protein electrophoresis

<table>
<thead>
<tr>
<th>Pattern</th>
<th>Minimal information to be provided in the interpretive comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal pattern</td>
<td>Normal pattern. Paraprotein not detected</td>
</tr>
<tr>
<td>Normal pattern (and clinical context suggests suspicion of plasma cell dyscrasia)</td>
<td>Normal pattern. Paraprotein not detected. Suggest urine protein electrophoresis and immunofixation, and/or serum free light chains if clinically indicated (if not already done/ordered)</td>
</tr>
<tr>
<td>Decreased alpha-1 globulins</td>
<td>Decreased alpha-1 globulins. Suggest alpha-1 antitrypsin quantitation and genotyping/phenotyping if clinically indicated</td>
</tr>
<tr>
<td>Decreased albumin and increased alpha-2 and beta globulins</td>
<td>Pattern is consistent with nephrotic syndrome (if corroborated by serum lipid results)</td>
</tr>
<tr>
<td>Increased alpha-1 and alpha-2 and/or gammaglobulins</td>
<td>Pattern is consistent with an acute inflammatory process</td>
</tr>
<tr>
<td>Increased beta-1 globulin (if IFE performed and paraprotein excluded)</td>
<td>Paraprotein not detected. If indicated, suggest iron studies</td>
</tr>
<tr>
<td>Polyclonal hypergammaglobulinaemia</td>
<td>A polyclonal increase in immunoglobulins is present</td>
</tr>
<tr>
<td>Polyclonal hypergammaglobulinaemia and acute phase pattern</td>
<td>Pattern is consistent with a chronic inflammatory process</td>
</tr>
<tr>
<td>Beta–gamma bridging</td>
<td>Beta–gamma bridging is present due to raised IgA or sometimes IgM. Causes may include cirrhosis, mucosal or cutaneous inflammation</td>
</tr>
<tr>
<td>Hypogammaglobulinaemia (first presentation)</td>
<td>Hypogammaglobulinaemia is present. Suggest serum immunofixation and urine protein electrophoresis including immunofixation (or serum free light chains) together with quantitation of total serum immunoglobulins (if not already done/ordered)</td>
</tr>
<tr>
<td>Hypogammaglobulinaemia (subsequent presentation)</td>
<td>Hypogammaglobulinaemia is present</td>
</tr>
<tr>
<td>Fibrinogen present</td>
<td>Fibrinogen present. Please send repeat serum specimen. (No clinical comment is required if laboratory can run a repeat serum specimen, otherwise needs IFE to ensure small band is fibrinogen and there is no underlying paraprotein; optimally needs repeat serum specimen as a small paraprotein cannot be quantitated by agarose gel SPEP when masked by the presence of fibrinogen)</td>
</tr>
<tr>
<td>Oligoclonal banding pattern with 2 or more bands on a polyclonal immunoglobulins background</td>
<td>Oligoclonal bands are present. This can occur in a number of infectious or autoimmune conditions. Suggest review in 3–6 months if clinically indicated</td>
</tr>
<tr>
<td>‘Inflammatory-type’ pattern with increased tubular proteins, i.e. alpha-1, alpha-2, and/or beta-2 microglobulins, and polyclonal FLC on IFE (‘ladder-type’ gamma pattern on UPEP)</td>
<td>Excess polyclonal free light chains present on immunofixation. Suggest repeat testing if clinically required when acute illness has resolved</td>
</tr>
</tbody>
</table>
Question 1

Which method do you use for serum protein electrophoresis?

A. Gel electrophoresis
B. Capillary electrophoresis

All labs are using Gel electrophoresis (7 responses)
Question 2

Which method do you use for serum immunotyping?

A. Immunofixation
B. Immunosubtraction

All labs are using immunofixation
Question 3

What is the most common approach in your laboratory in order to screen an individual for the presence of a monoclonal gammopathy in the initial evaluation?

A. Serum protein electrophoresis only
B. Serum protein electrophoresis with reflex to immunofixation or immunosubtraction
C. Serum protein electrophoresis and immunofixation or immunosubtraction
D. Serum protein electrophoresis combined with serum protein immunofixation and serum free light chain
E. Serum protein electrophoresis and urine examination for Bence-Jones protein

A. None
B. 4
C. None
D. 2
E. 1
Question 4

Do you perform screening using urine protein electrophoresis?

- Yes
- No

- A – Six labs
- B- One lab (only when clinician request)
Question 5

Which method do you use to quantitate a paraprotein in the gamma region on serum protein electrophoresis?

A. Perpendicular (orthogonal)

B. Corrected perpendicular

C. Tangent skimming (valley to valley)

D. Other (please specify)

All labs are using Perpendicular gating – Seven labs
Question 6

What would be the next test that you do if you detect a monoclonal band in the beta region?

A. Immunofixation
B. Immunosubtraction
C. Other (please specify)

All labs proceed with immunofixation

Follow up of these patients?
Question 7

The nomenclature used in reporting monoclonal component detected in protein electrophoresis

A. Paraprotein
B. Monoclonal protein
C. M-protein
D. M-band
E. M-spike
F. Monoclonal immunoglobulin

All labs use paraprotein to report monoclonal component
Question 8

Do you report the other fractions of serum protein electrophoresis?

A. Yes
B. No

All labs report other fractions
Question 9

Do you report total immunoglobulin concentration with protein electrophoresis (e.g. IgG, IgA or IgM)?

A. Yes
B. No

A. 3 labs
B. 4 labs
Question 10

Please specify the decimal places reported in quantitative fractions

A. None
B. One
C. Two

A. 1
B. 4
C. 2
Question 11

**Albumin reporting**
A. BCG or BCP method
B. Based on Serum protein electrophoresis

A. 3
B. 4
Question 12

Number of decimal places used in reporting monoclonal protein if the quantitation is more than 10g/L

A. None
B. One

A. 1
B. 6
Question 13

Number of decimal places used in reporting monoclonal protein if the quantitation is less than 10g/L

A. None
B. One

A. 1
B. 6
Question 14

How do you report the concentration of a medium to large monoclonal protein in the beta region on serum protein electrophoresis?

A. Monoclonal protein concentration
B. Monoclonal protein concentration after subtracting a predetermined value for beta (beta-1 or beta-2)
C. ‘Monoclonal protein + total beta’

A. 3
B. None
C. 4
Question 15

How do you report a small paraprotein in the beta region that cannot be distinguished from the normal beta proteins?

A. None by two labs
B. 5 labs do immunofixation and report beta quantitation
Question 16

Does your report mention about multiple monoclonal protein?

A. Yes
B. No

A. 5
B. 2
Question 17

Do you report monoclonal protein less than 1g/L?

A. Yes
B. No

A. 4
B. 3
Question 18

Do you report quantitative electrophoretic result changes comparing to previous measurements on the same patient?

A. Yes
B. No

A. 5
B. 2
Question 19

Does your lab report significant change in the value of monoclonal protein?

A. Yes
B. No

A. 4
B. 3
Question 20

When do you call it as a significant change? Specify

1. None - 4
2. 15% change
3. 50% change - 3
Question 21

How do you report a normal serum protein electrophoresis pattern? Select all that apply

A. Normal pattern
B. Normal pattern. M-protein not detected

All labs report Normal pattern. Monoclonal protein not detected
Question 22

Do you report other pathological patterns?

A. Yes
B. No

All labs report other pathological patterns
Question 23

How do you report an oligoclonal banding pattern with 2 or more small bands on a polyclonal Ig background on serum protein electrophoresis?

A. Oligoclonal bands are present
B. Oligoclonal bands are present. This can occur in a number of infectious or autoimmune conditions.
C. Suggest review in 3–6 months if clinically indicated

A. A,B,C – 3 labs
B. B,C – 2 labs
C. B- 1
D. C-1
Question 24

Does your lab report about the interferences to the clinician?

A. Yes
B. No

A. 4
B. 3
Question 25

Do you report small abnormal band (1g/L) seen for the first time in a patient with no known monoclonal gammopathy?

A. Yes
B. No

A. 5
B. 2

Comment: Terminology used faint paraprotein to correlate with clinical and CRAB
Question 26

Do you report a new, small abnormal band with different electrophoretic mobility from the original M-protein in a patient with a known M-protein?

A. Yes  
B. No

A. 6  
B. 1

All labs mention about class switching (confirmed by IFE) to correlate with clinical and other investigations.
Conclusion

• There need to be consensus in reporting of protein electrophoresis by Malaysian laboratories.
• These are the initial audit findings
• Hoping that this may lead to standardized reporting of serum protein electrophoresis