# WG-ICQA
# Harmonisation of Interpretive Commenting EQA

## WG-ICQA Subgroup:

## Harmonisation of reporting of protein electrophoresis and serum FLC, and quantification of small monoclonal proteins

- Improved patient safety and to promote alignment with clinical guideline practices
  - previous surveys in several countries indicate a lack of harmonisation in all related testing phases
- International baseline survey to inform protein laboratories globally of current practices
- 30 questions addressing specific aspects of pre-analytical, analytical and post-analytical phases of Total Testing Process
- To issue a survey report and to write a Position Paper on minimum recommended harmonised laboratory practices.

# Survey questions

## Sections A & B: Pre-analytical phase (6 Qs)

- Guidelines and test requesting for diagnosis of monoclonal gammopathies
- Guidelines and test requesting for monitoring disease response in monoclonal gammopathies

## Section C: Analytical phase (11 Qs)

- Monoclonal IgD/E identification
- Analytical interference by therapeutic mAb immunotherapy
- Quantification

## Section D: Post-analytical phase (8 Qs)

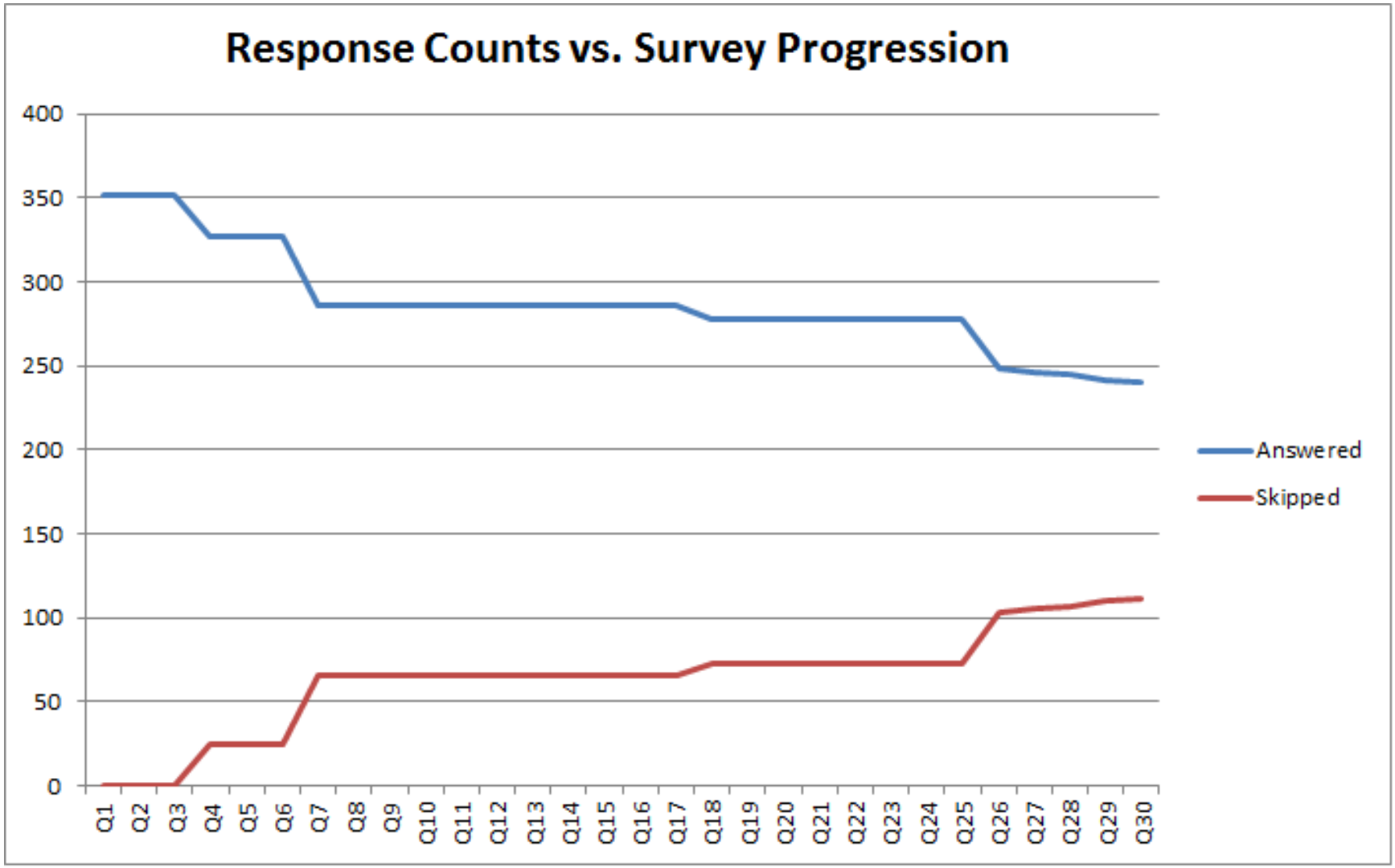
- Reporting
- Interpretive commenting

## Section E: Demographics (5 Qs)

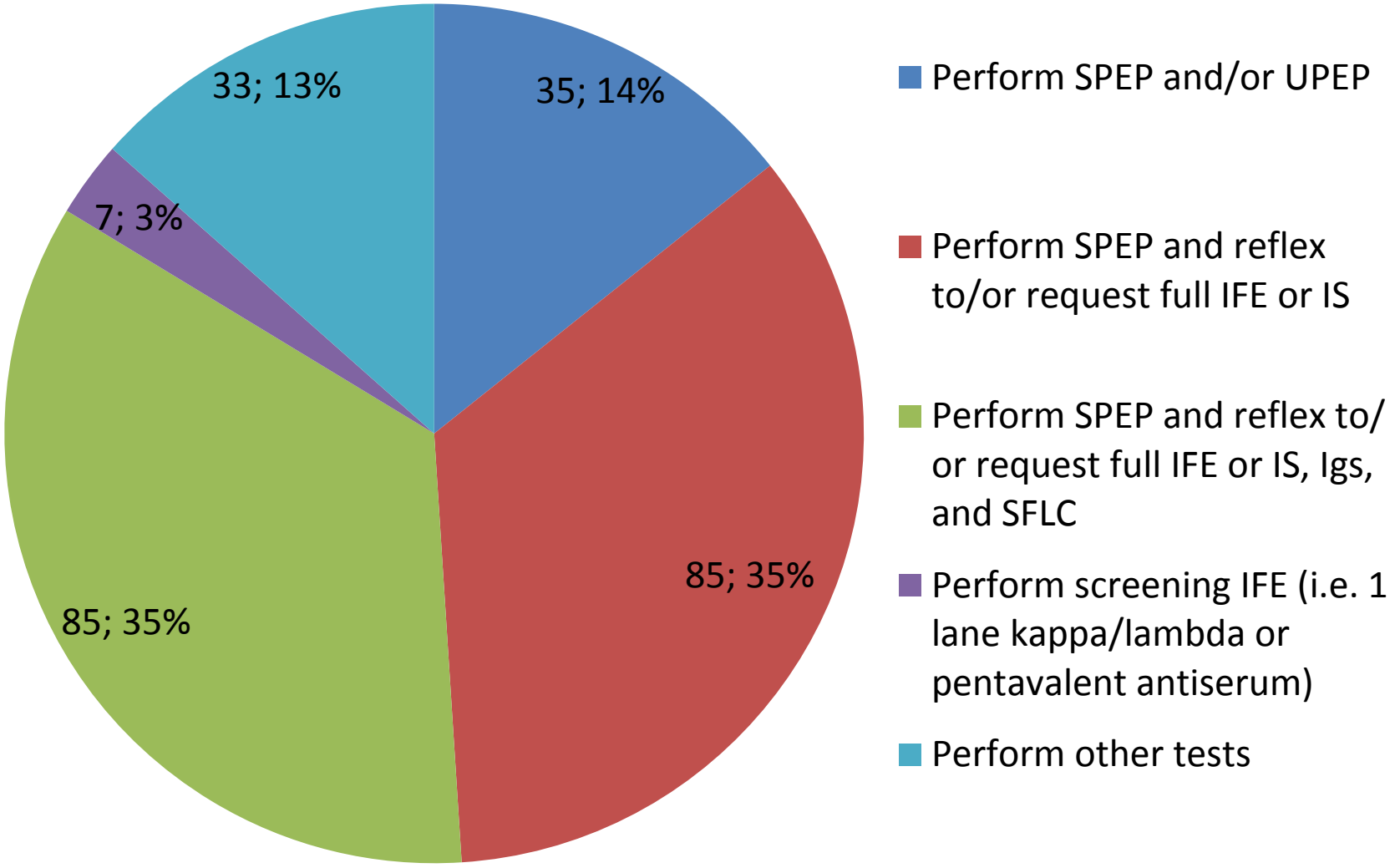
| | |
|---|---|
| ALBANIA | 1 |
| ARGENTINA | 1 |
| AUSTRALIA | 23 |
| BRAZIL | 2 |
| CANADA | 1 |
| CROATIA | 6 |
| CZECH REPUBLIC | 2 |
| ESTONIA | 1 |
| FINLAND | 3 |
| HONG KONG | 1 |
| HUNGARY | 1 |
| INDIA | 2 |
| IRELAND | 1 |
| ITALY | 83 |
| JAPAN | 5 |
| KOREA | 1 |
| MALAYSIA | 1 |
| MOROCCO | 1 |
| NETHERLANDS | 22 |
| NEW ZELAND | 4 |
| PAKISTAN | 1 |
| SERBIA | 1 |
| SLOVAK REPUBLIC | 2 |
| SOUTH AFRICA | 3 |
| SPAIN | 1 |
| SWEDEN | 15 |
| SWITZERLAND | 6 |
| SYRIAN ARAB REPUBLIC | 1 |
| TURKEY | 5 |
| UK | 42 |
| UNITED STATES OF AMERICA | 6 |
| (No country given) | 102 |

245 labs from 31 countries.
347 labs participated

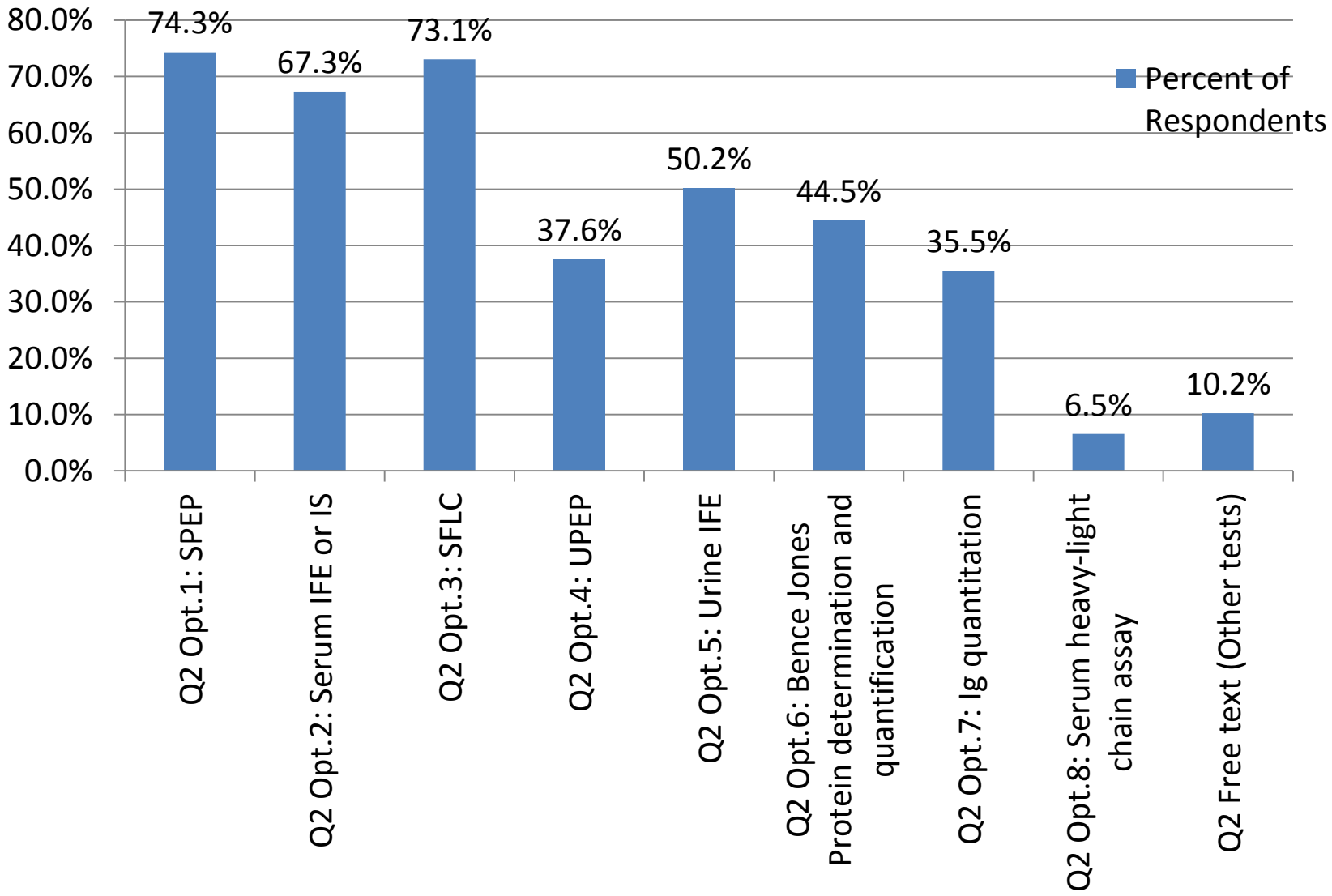
# Response rates to questions



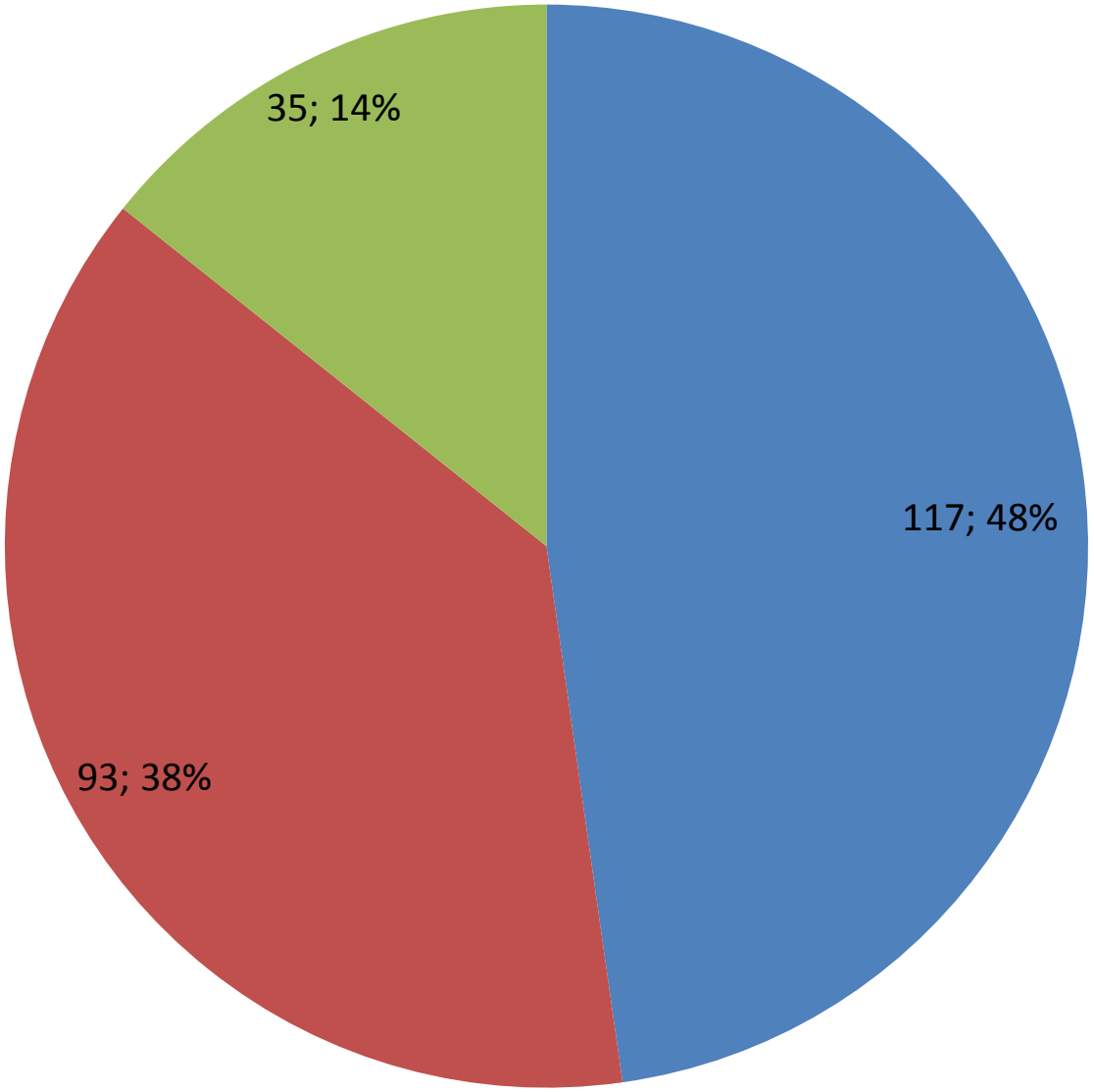
Q1: If you are asked to screen for a monoclonal gammopathy, which of the following describe best your laboratory procedure?



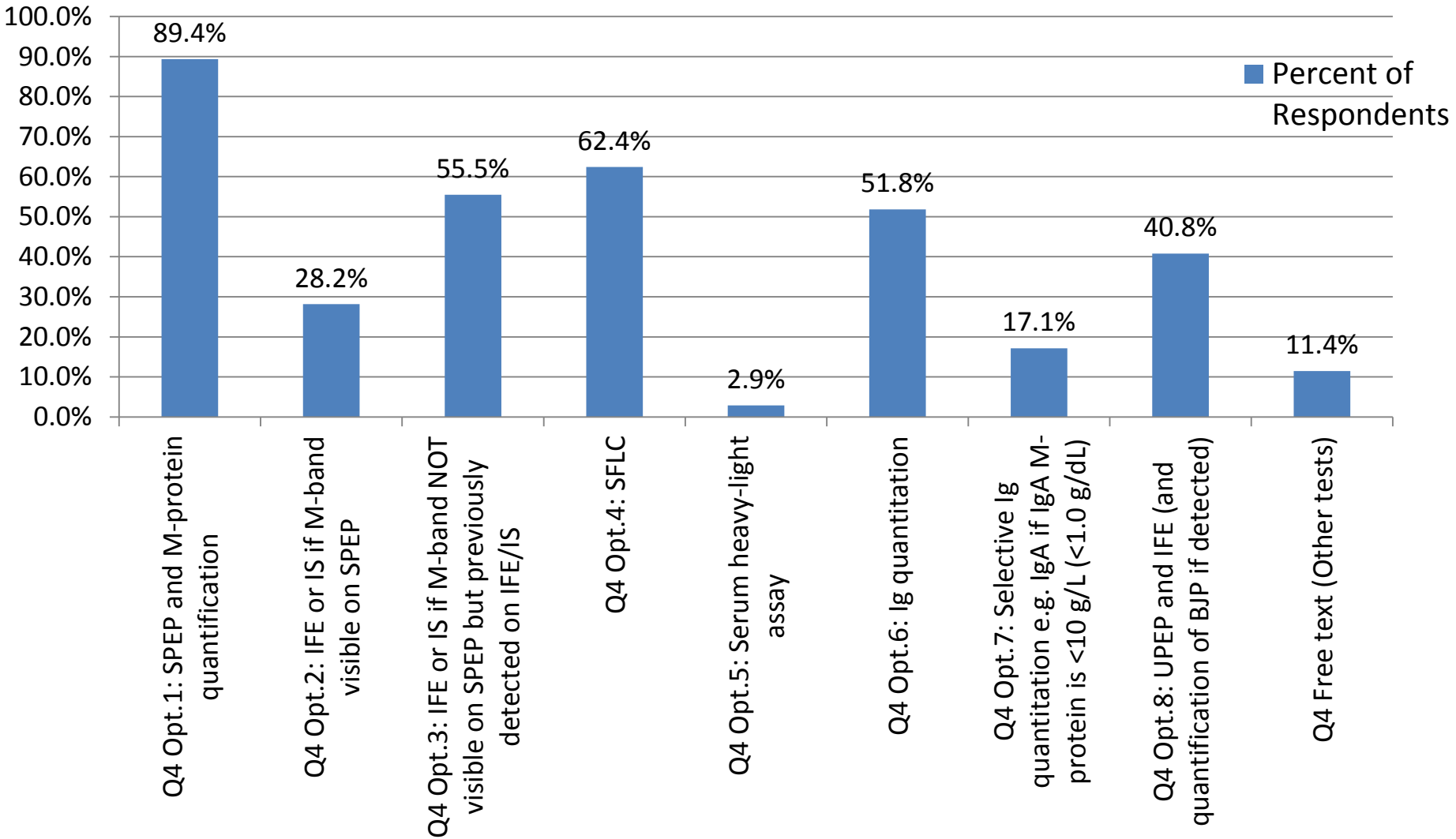
# Q2: What tests are used in your institution to diagnose AL amyloidosis cases? Select all that apply.



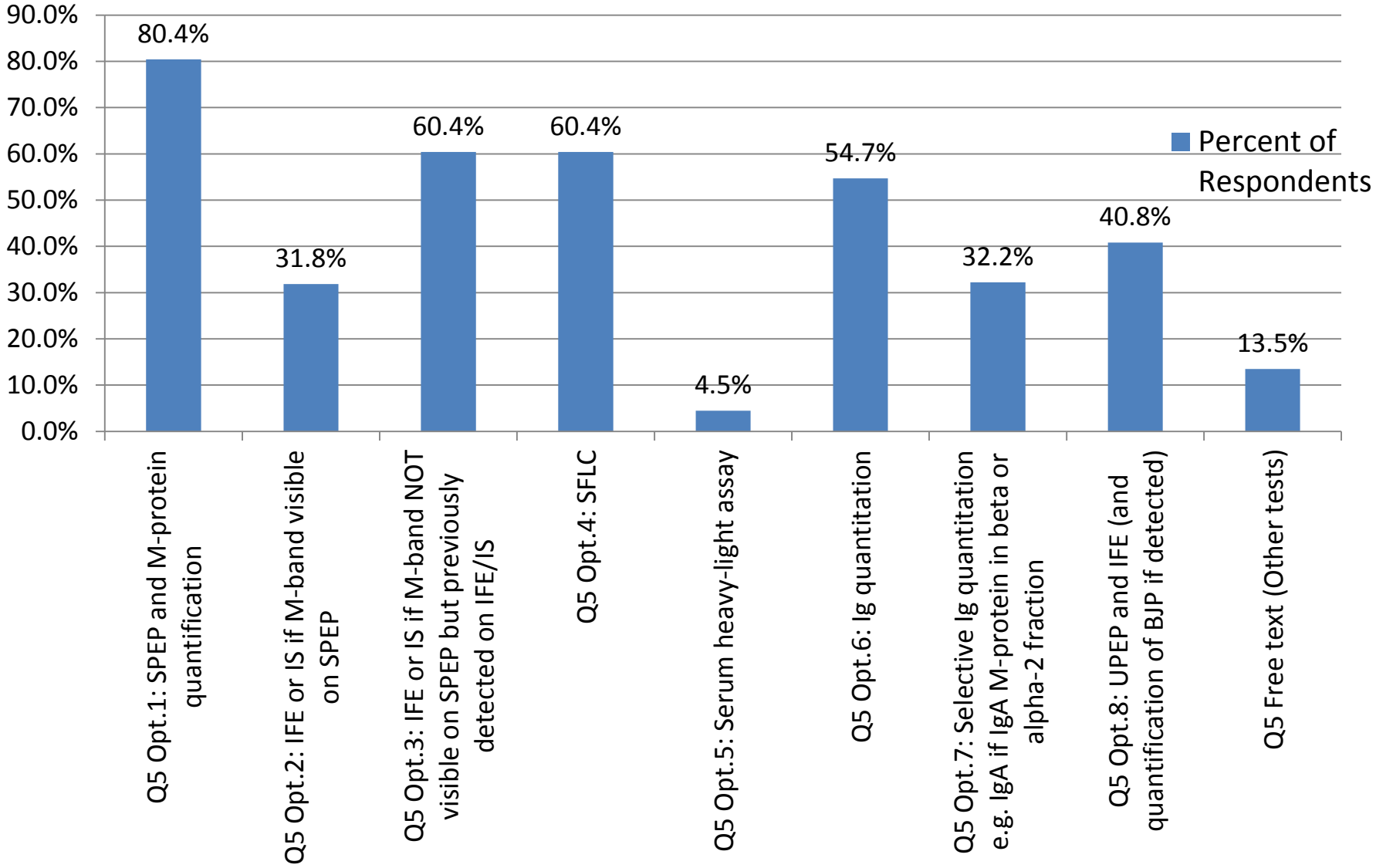
# Q3: How do you offer this laboratory diagnostic in your Institution?



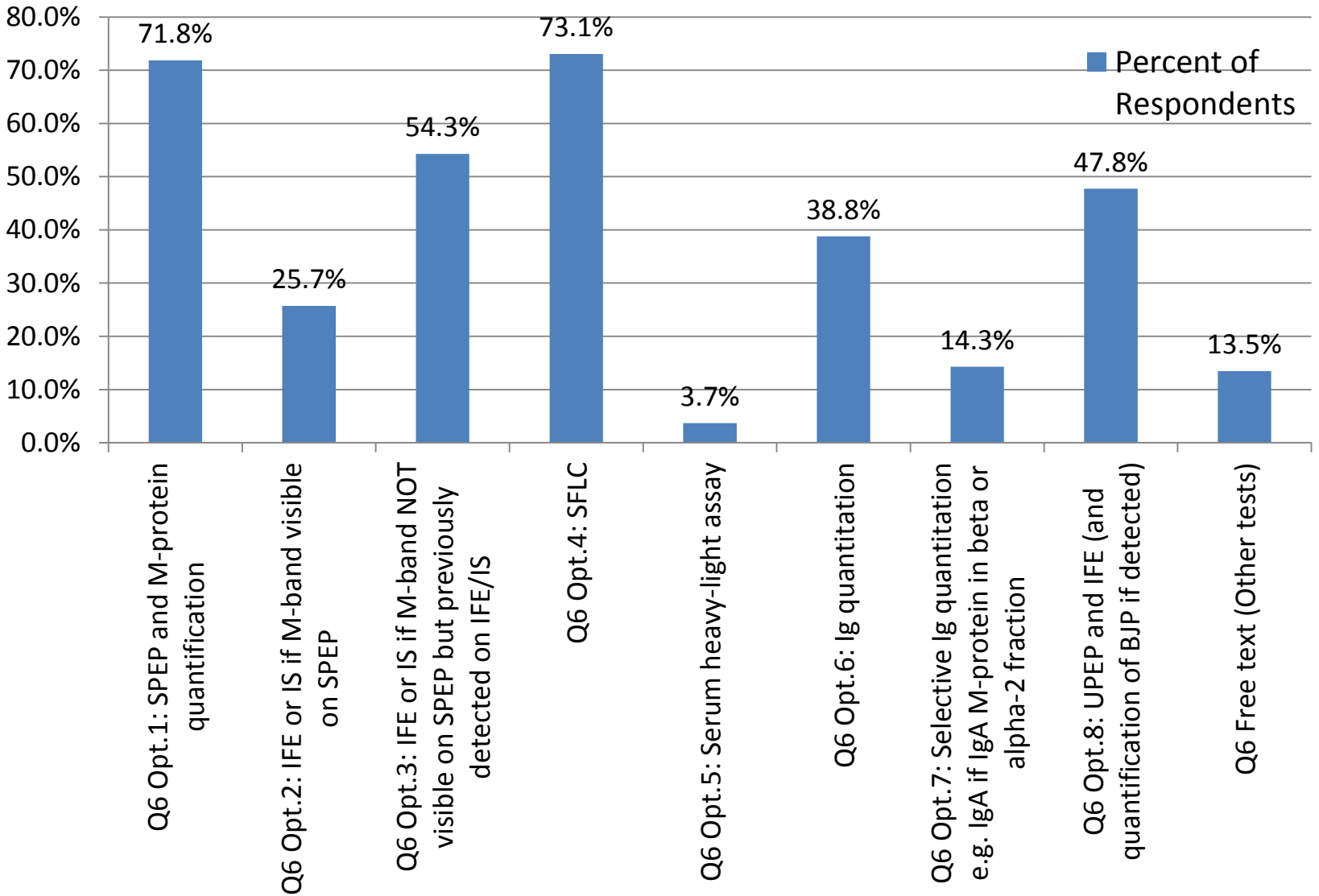
# Q4: What tests are used in your institution to follow-up a treated myeloma case with the M-protein migrating in the gamma fraction? Select all that apply.



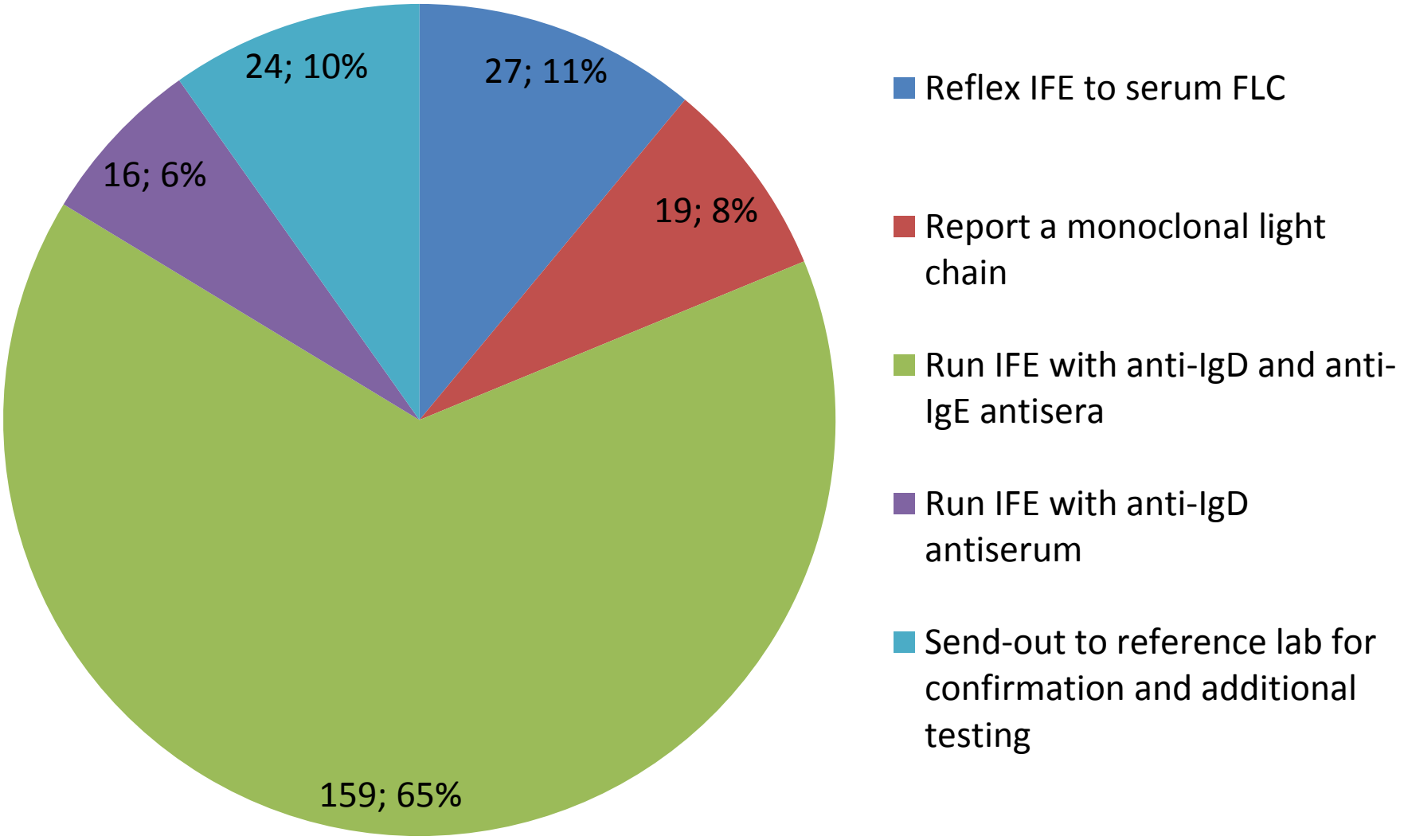
# Q5: What tests are used in your institution to follow-up a treated myeloma case with the M-protein migrating in the beta or alpha-2 fraction? Select all that apply.



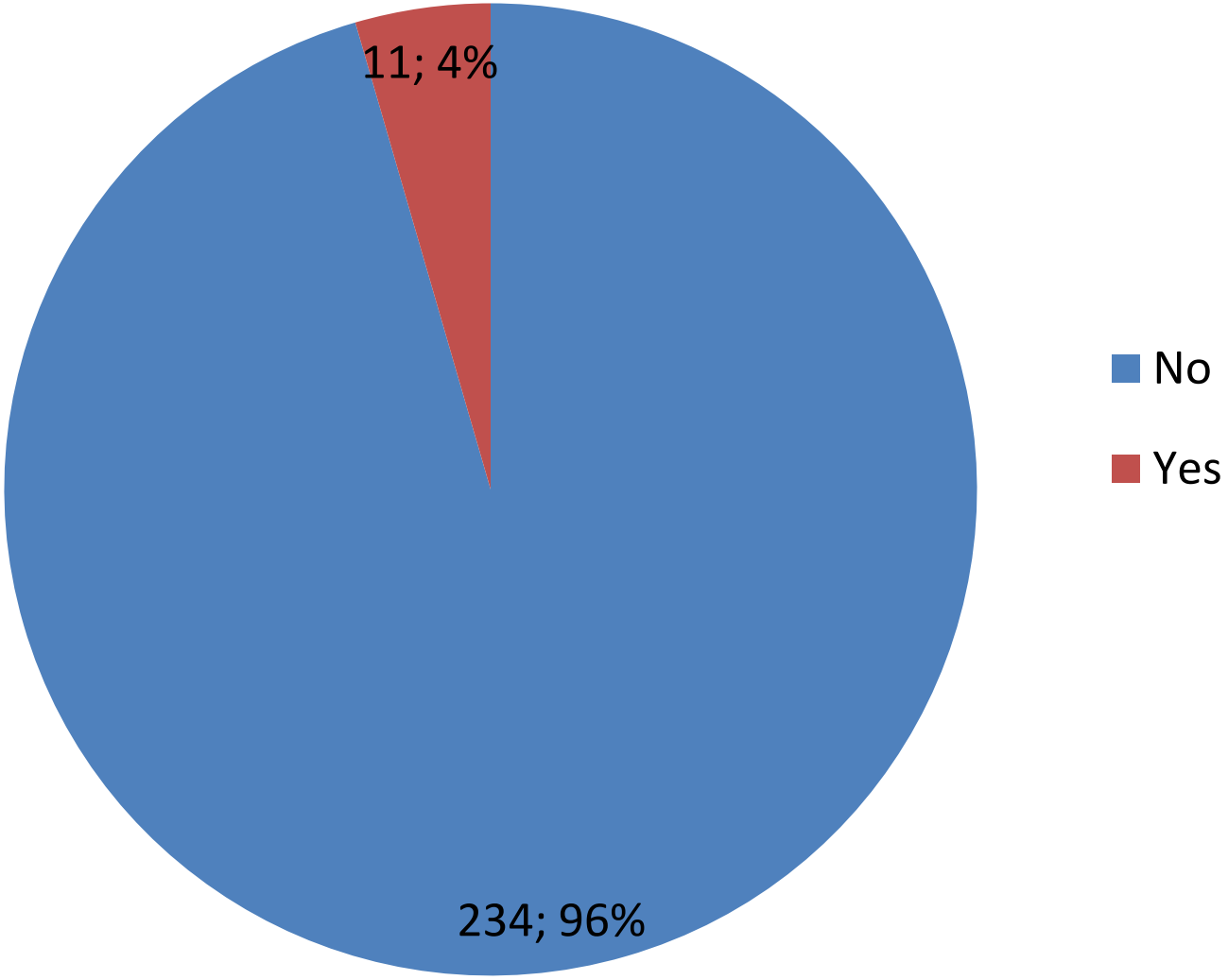
# Q6: What tests are used in your institution to follow-up a treated AL amyloidosis case? Select all that apply



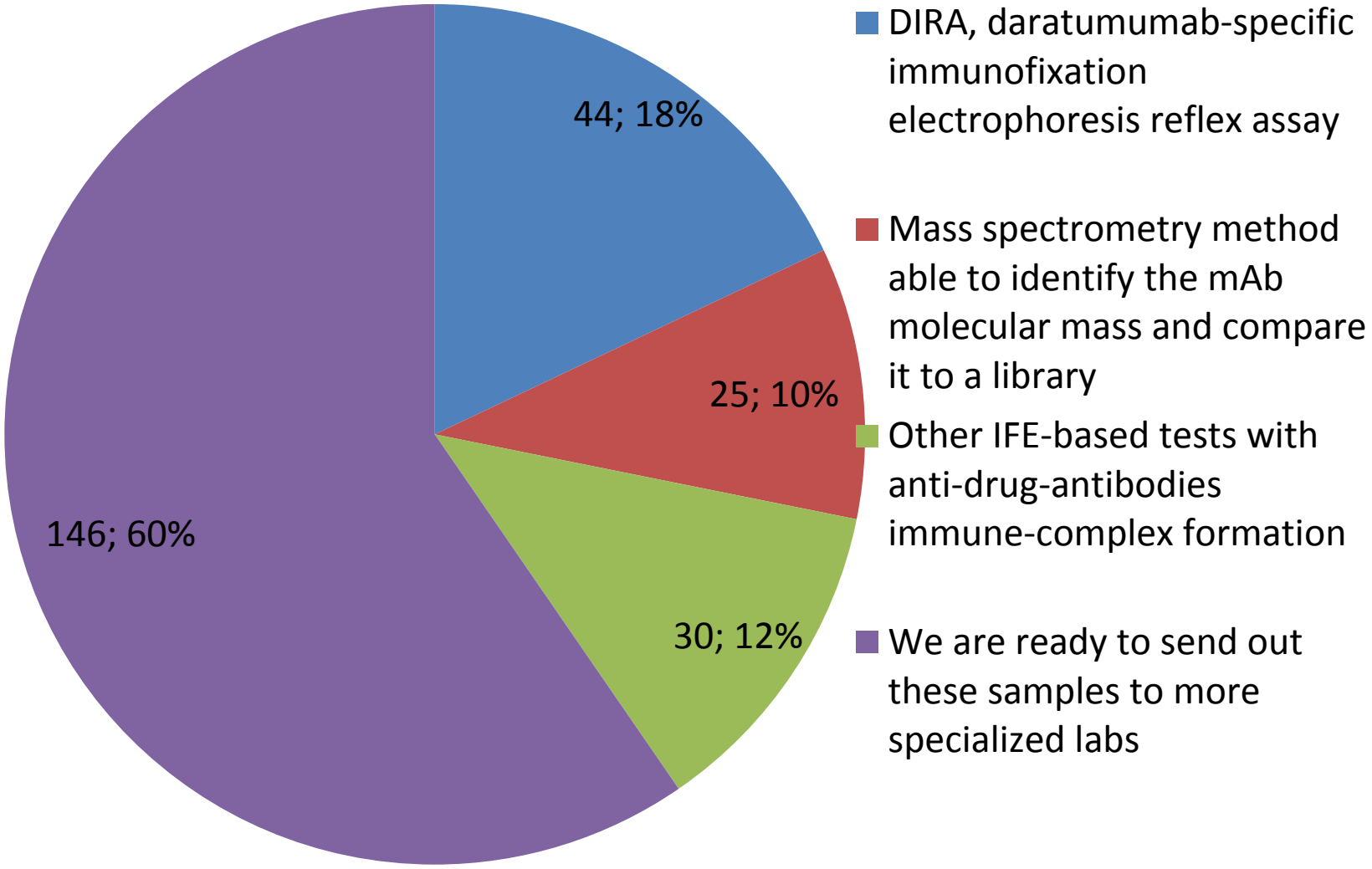
Q7: Once a light chain (kappa or lambda) is identified on serum IFE or IS without a corresponding heavy chain for the first time, with no available history, what is the next step?



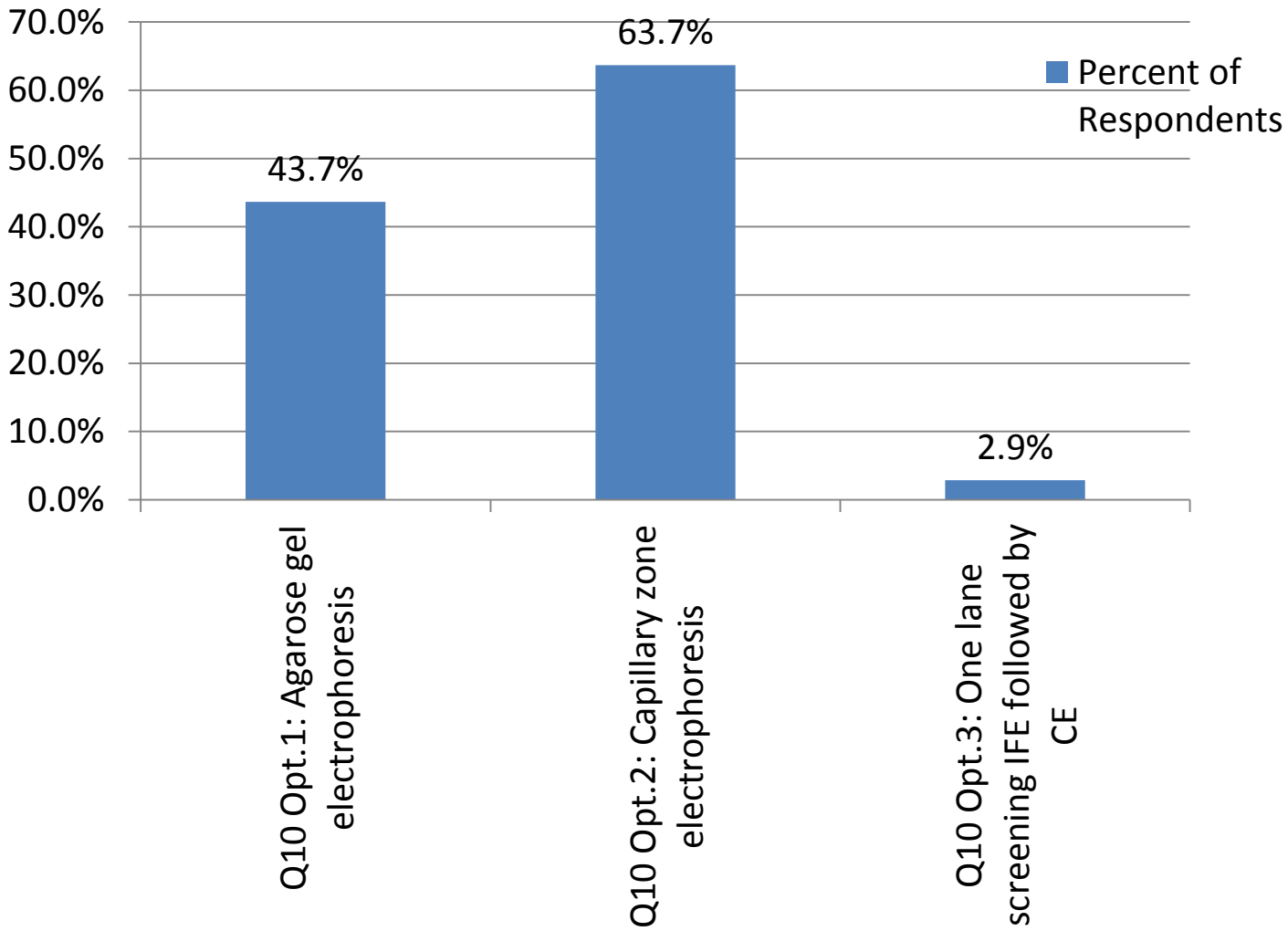
Q8: Do you perform any routine testing to distinguish between an endogenous M-protein and a therapeutic mAb?



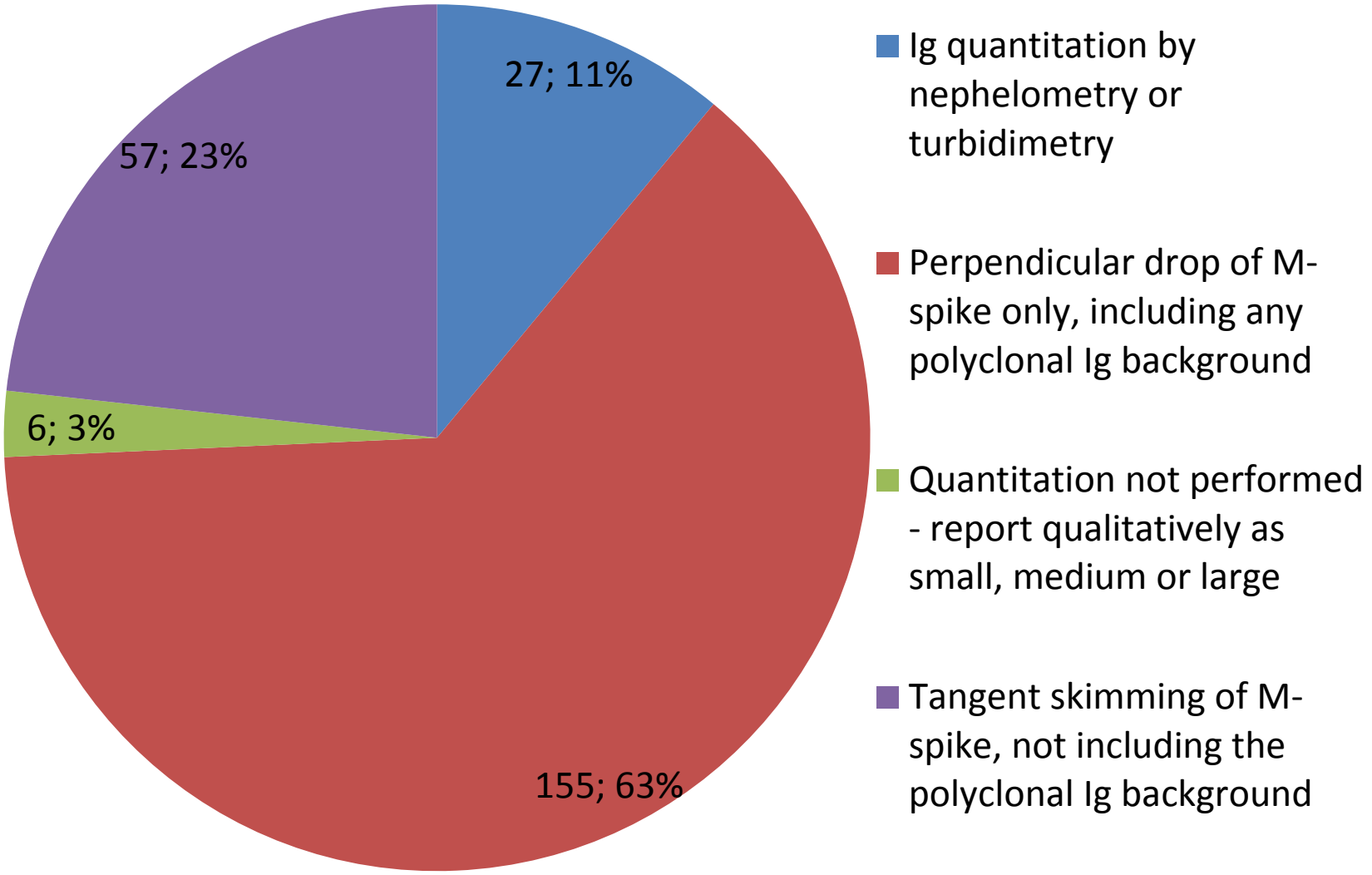
# Q9: Which method do you use (or think will be able to use in the future) to detect this interference?



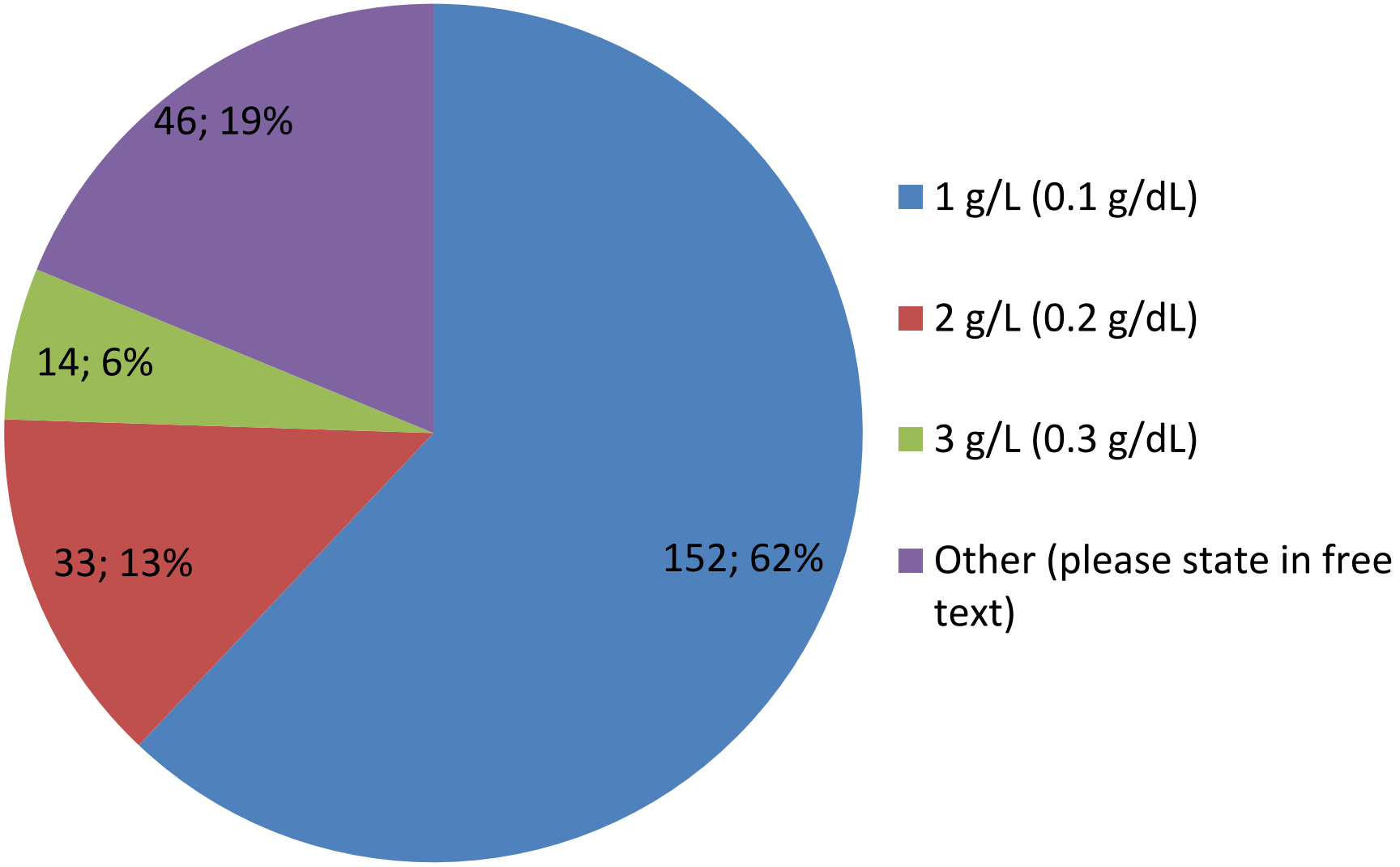
# Q10: What methods do you use for SPEP? (select all that apply)



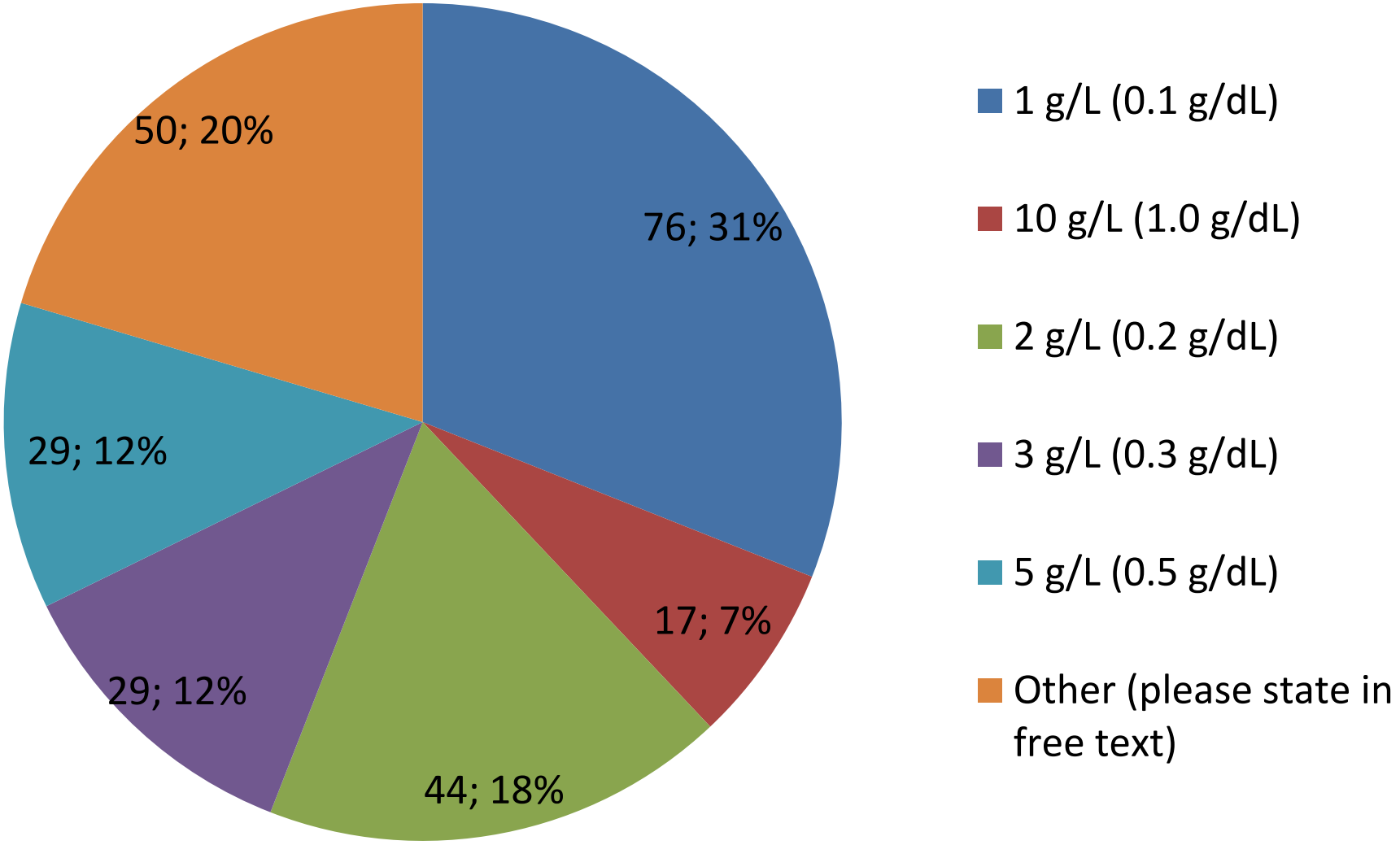
# Q11: How do you currently quantitate the M-protein migrating in the gamma fraction?



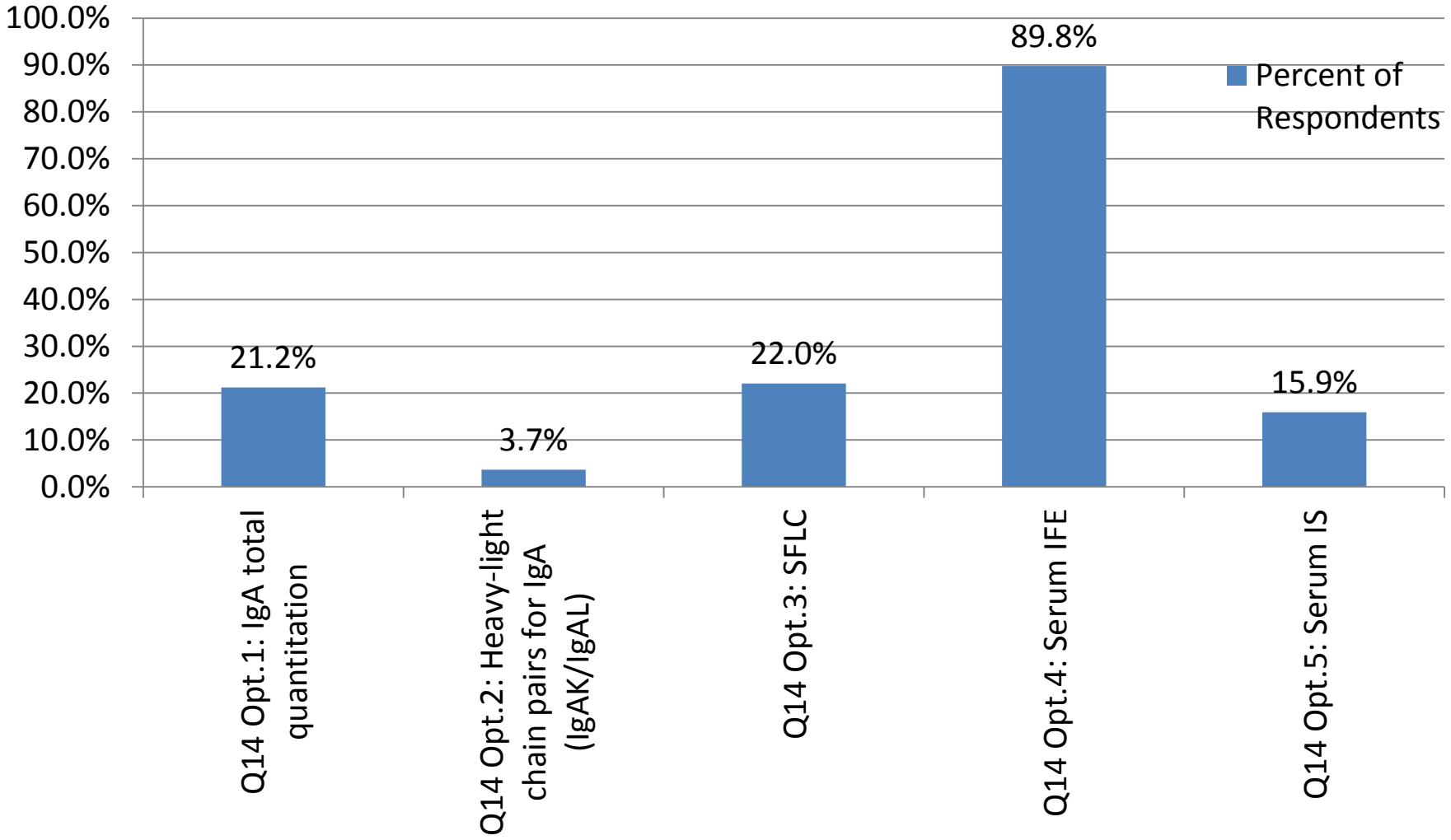
Q12: What is your method's limit of detection of an M-protein migrating in the gamma fraction on a low polyclonal Ig background of less than 5 g/L (0.5 g/dL). Select one concentration.



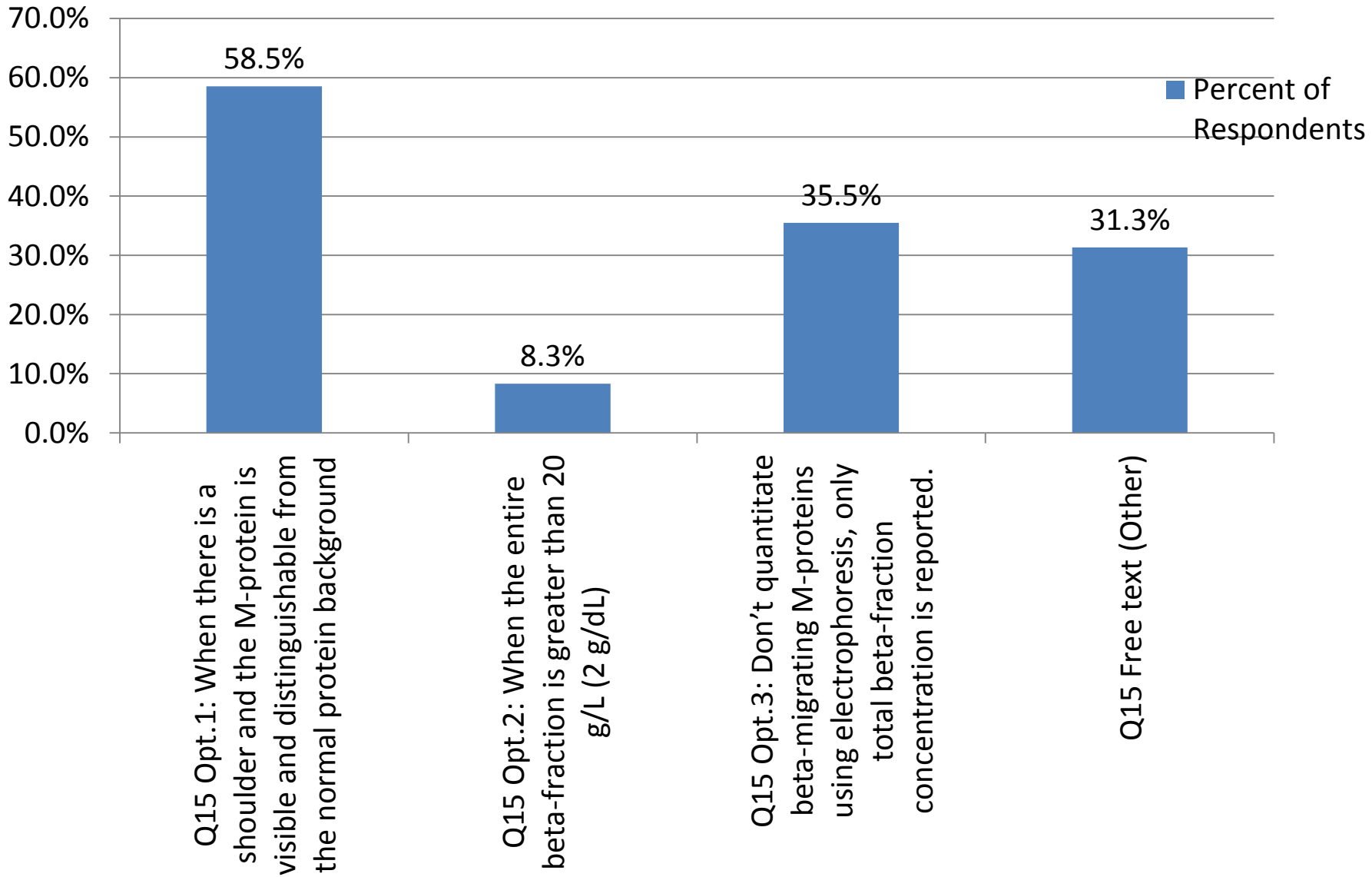
Q13: What is your method's limit of detection of an M-protein migrating in the gamma fraction on an elevated polyclonal Ig background of greater than 20 g/L (2.0 g/dL). Select one concentration



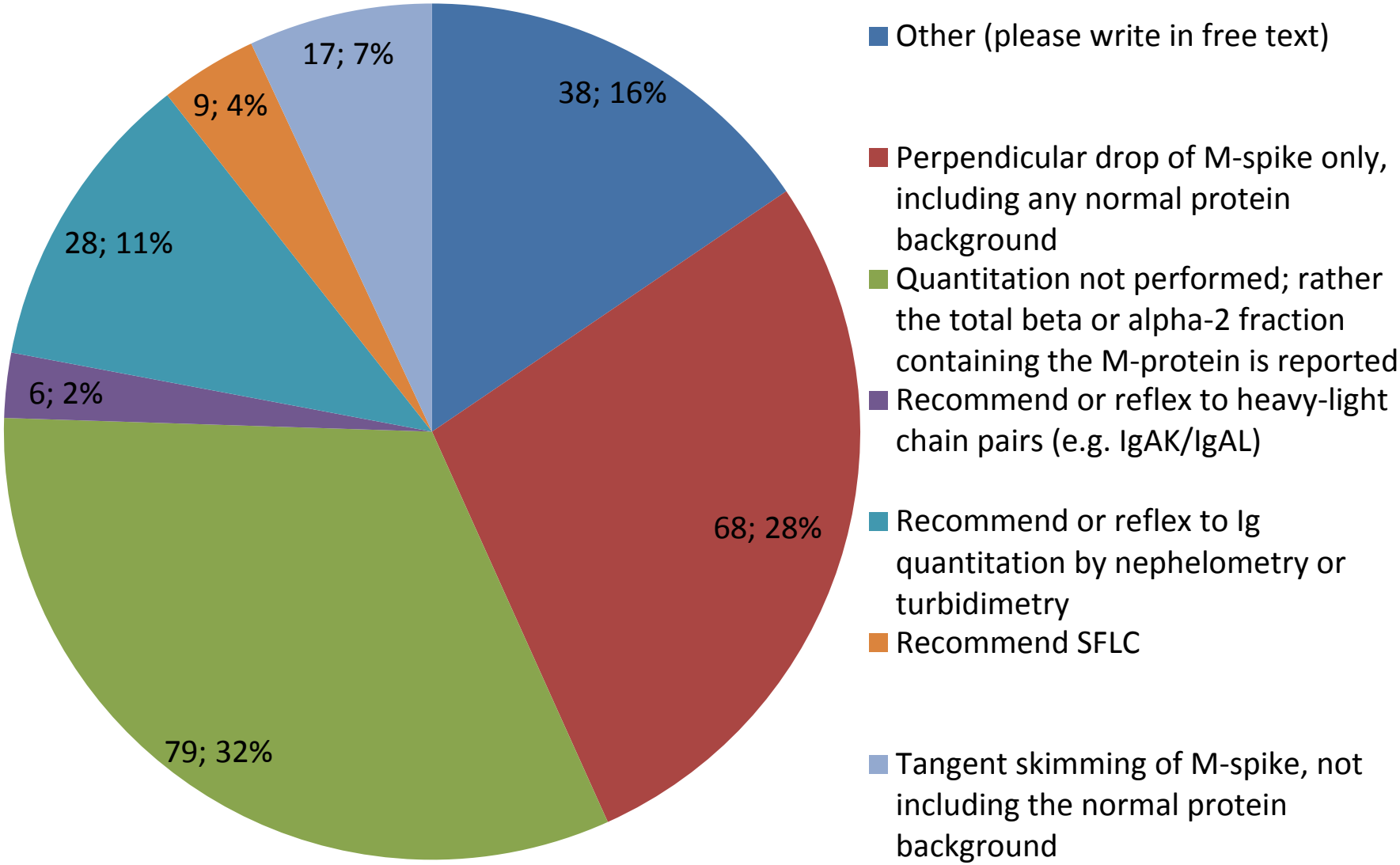
# Q14: If beta or alpha-2 fraction is increased or abnormal, but not enough for you to quantitate it, and a monoclonal gammopathy is suspected, what are the next tests that you would suggest to be performed? Select all that apply.



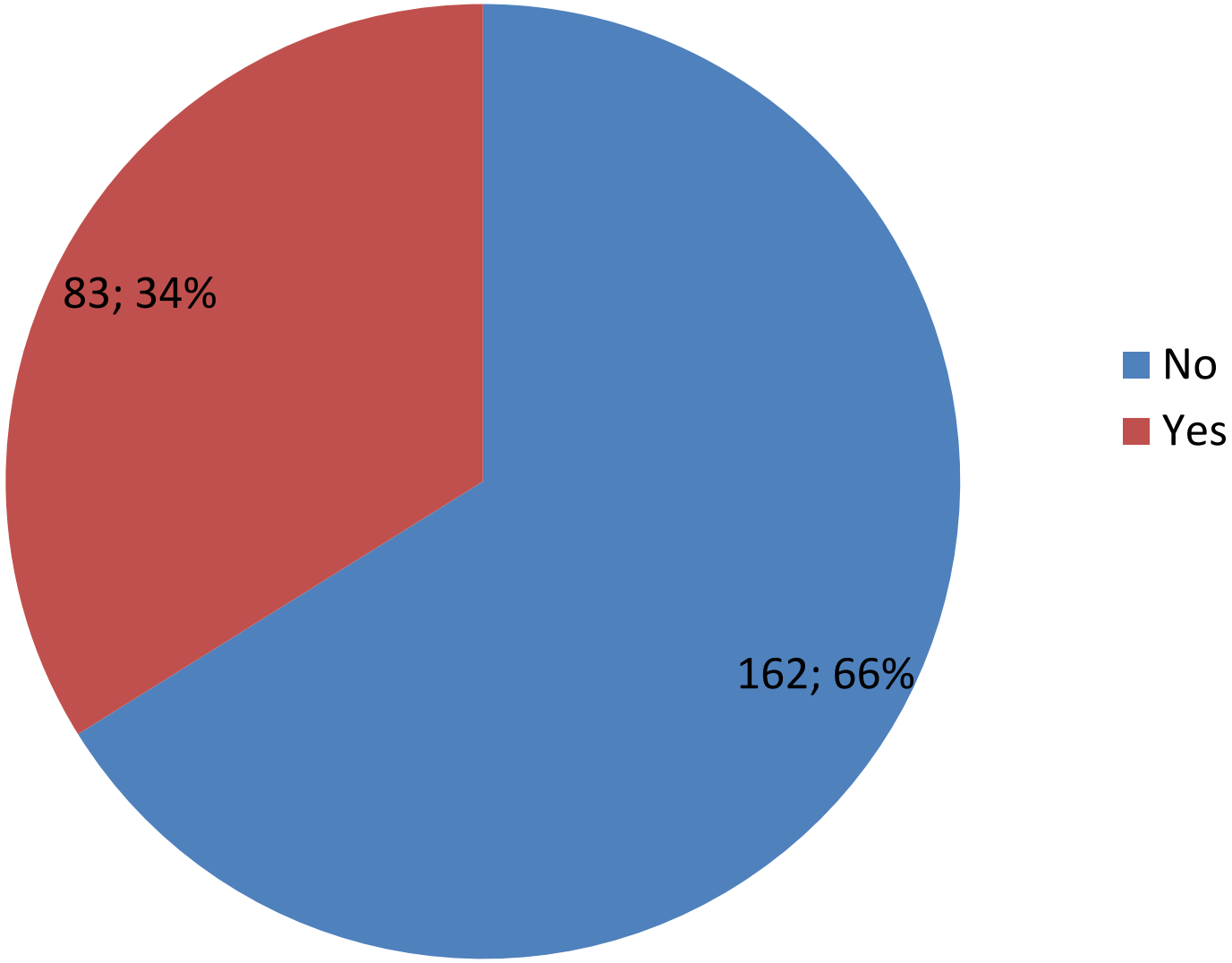
# Q15: When do you quantitate the beta-fraction or beta-1 and beta-2 fractions? Select all that apply



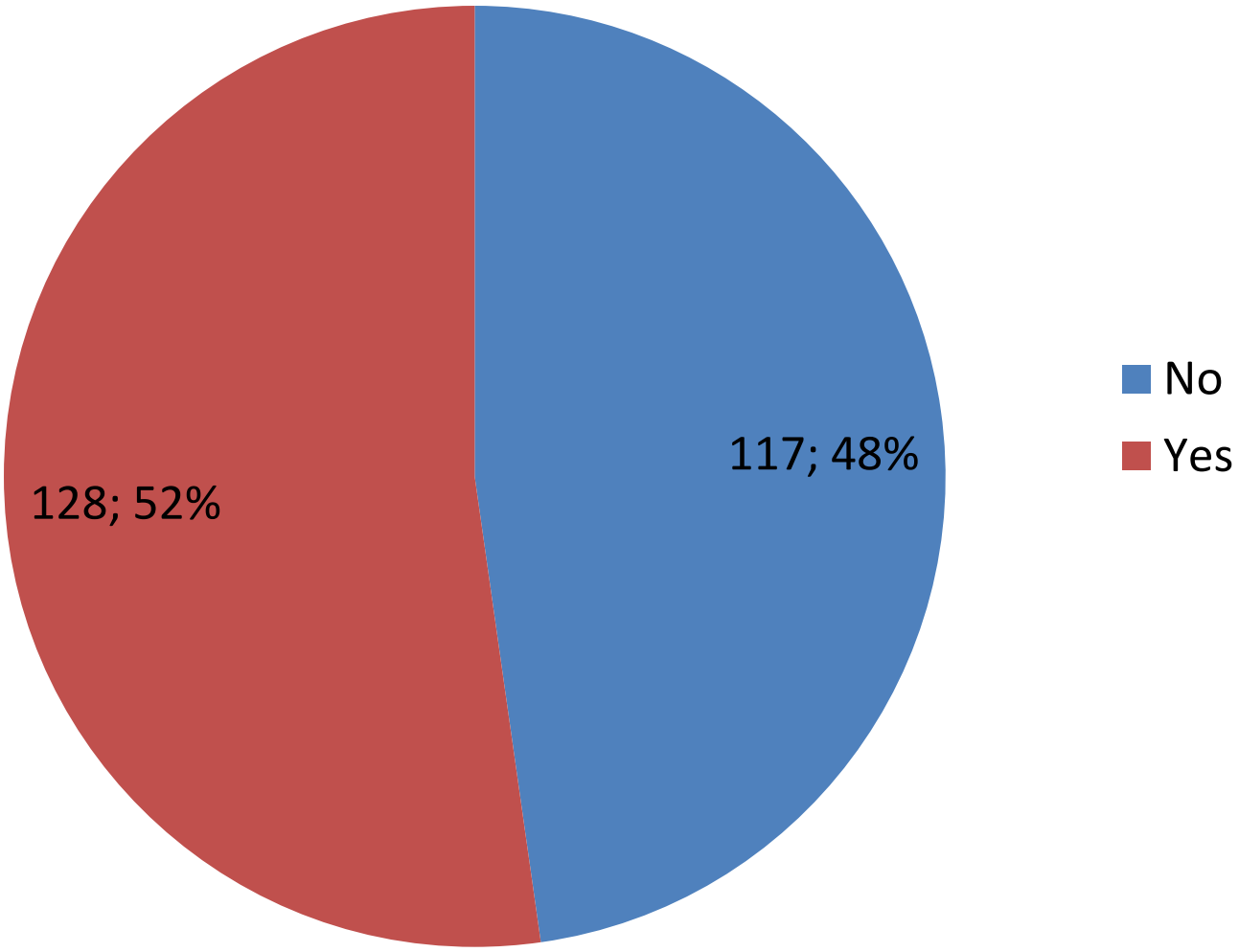
# Q16: How do you quantify M-proteins overlapping normal proteins in the beta and alpha-2 fractions when the M-protein is not clearly separated?



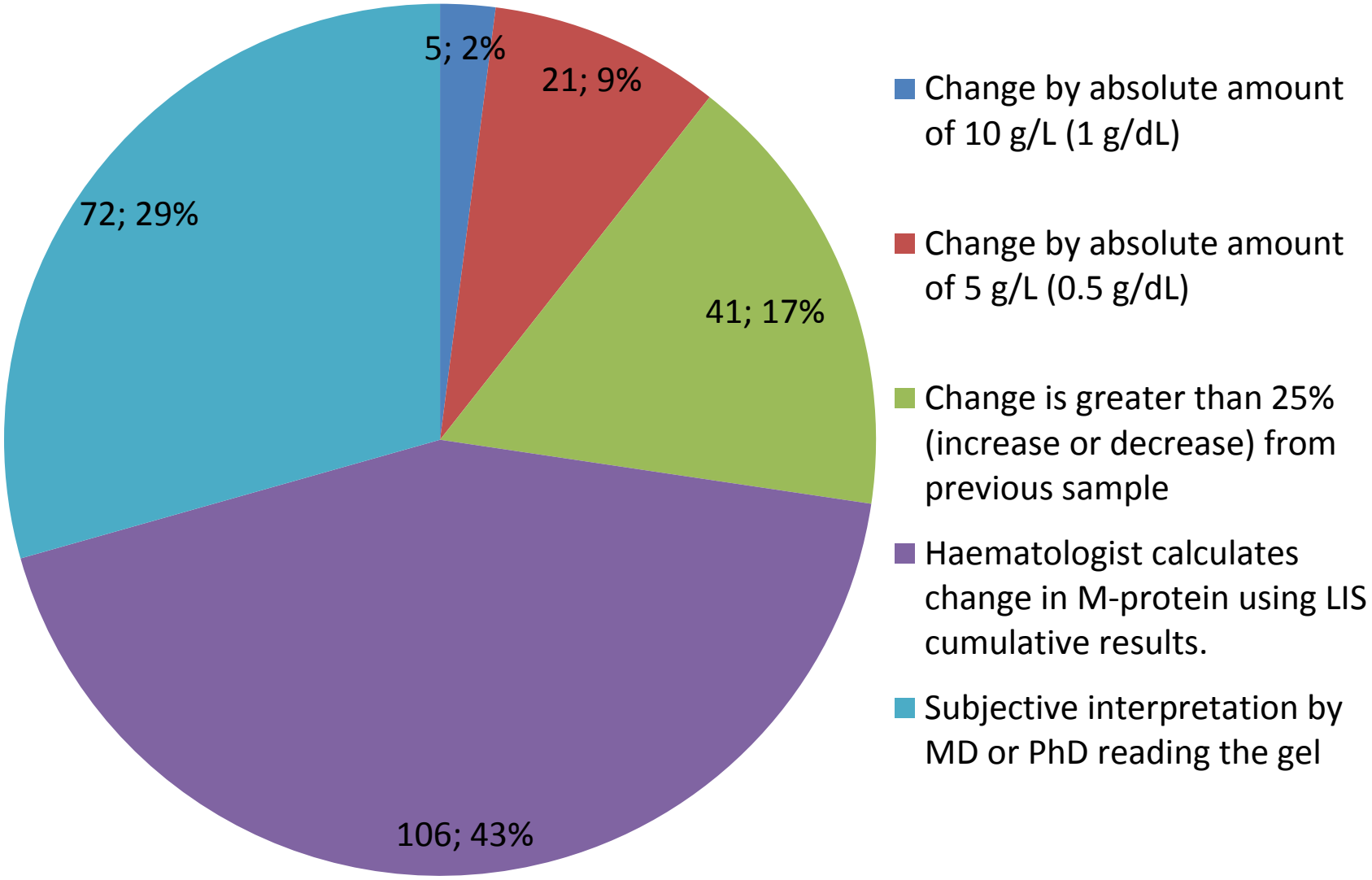
Q17: Does your institution conduct a periodic ‘gating’ challenge among operators to assess variation in M-protein quantitation?



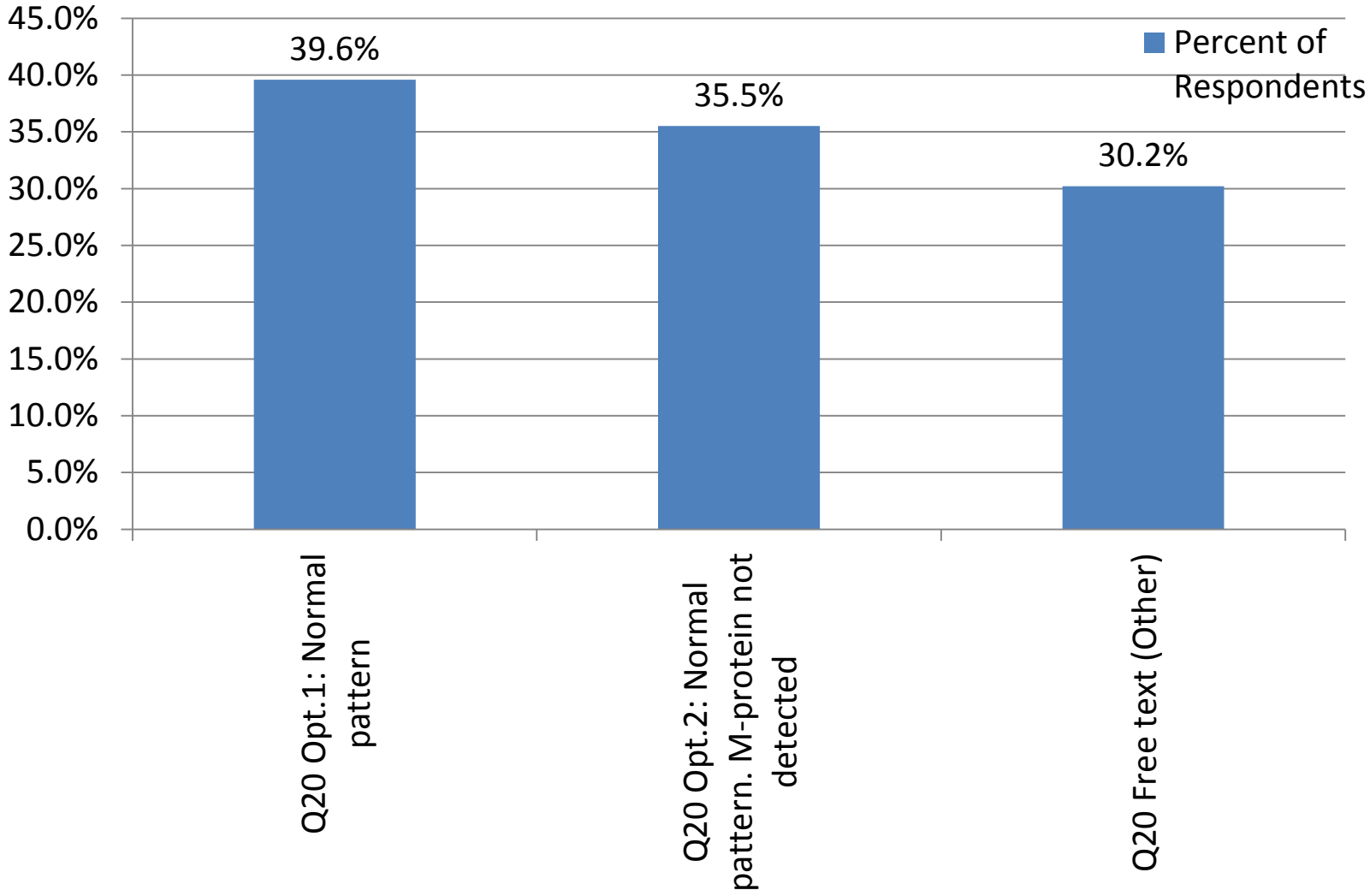
Q18: Do you report quantitative electrophoretic result changes comparing to previous measurements on the same patient?



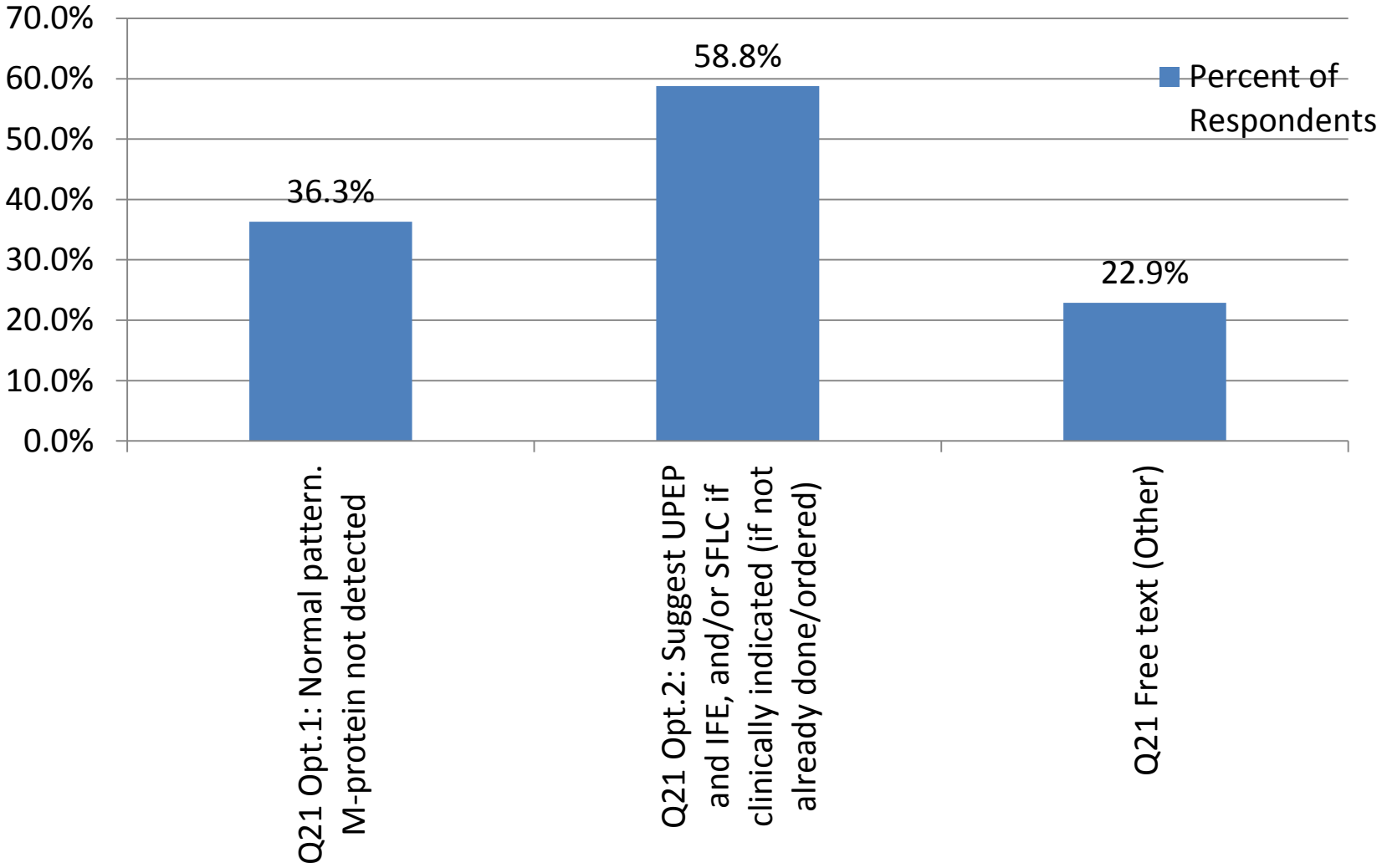
# Q19: If yes, when do you consider an M-protein change significant?



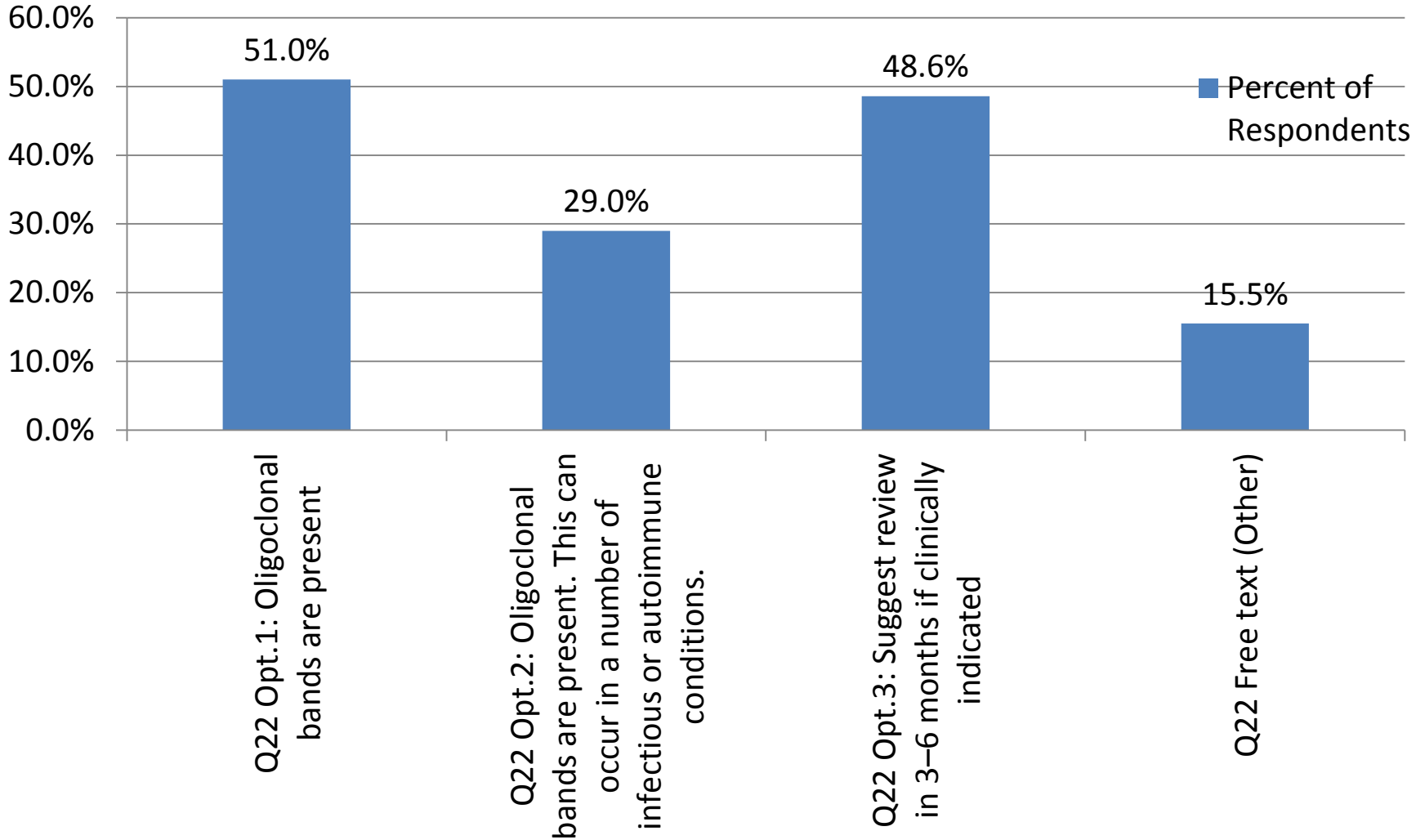
# Q20: How do you report a normal serum protein electrophoresis pattern? Select all that apply



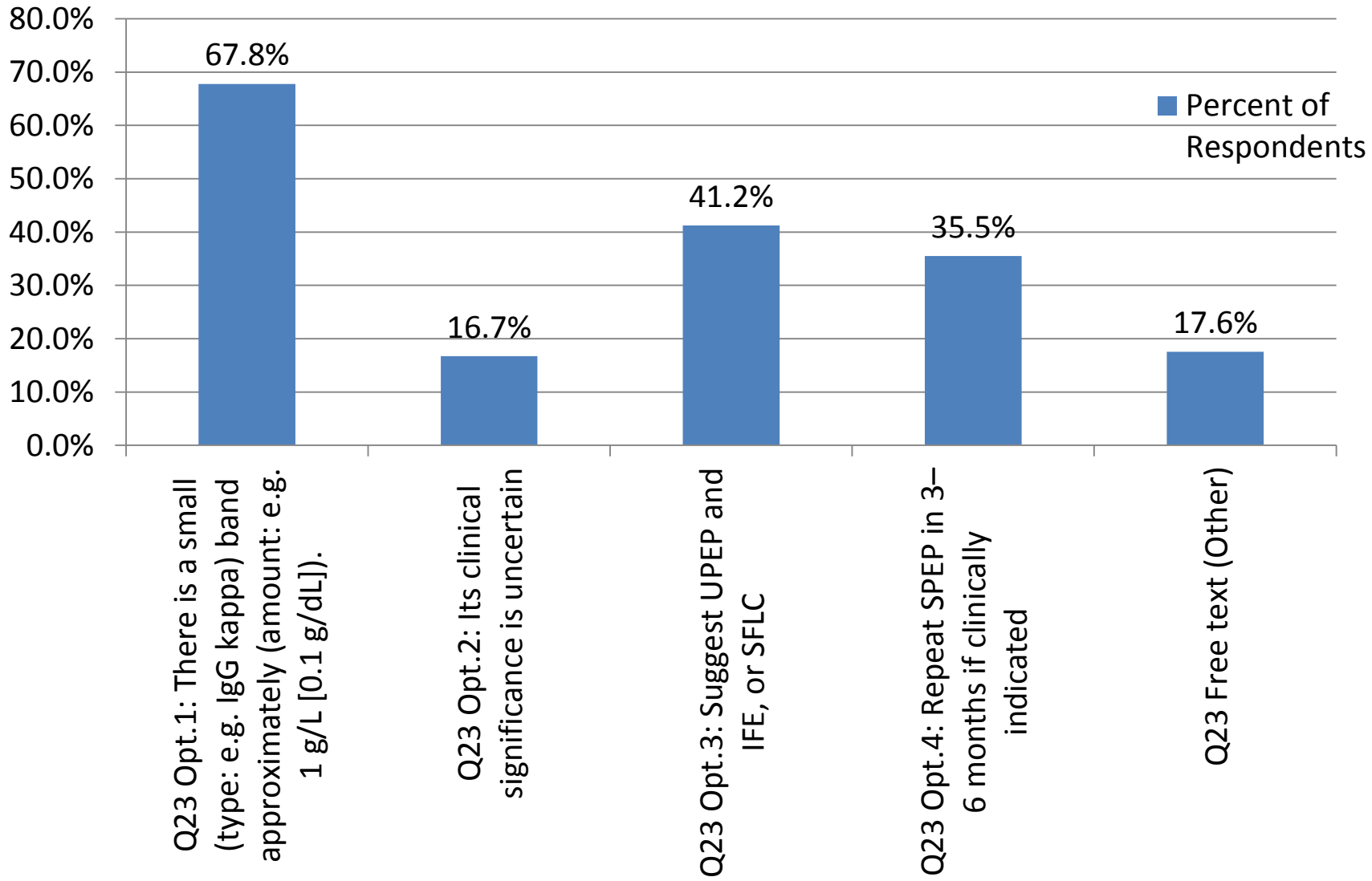
# Q21: How do you interpret a normal serum protein electrophoresis pattern (if ordered as a standalone test) but the clinical context suggests suspicion of plasma cell dyscrasia? Select all that apply.



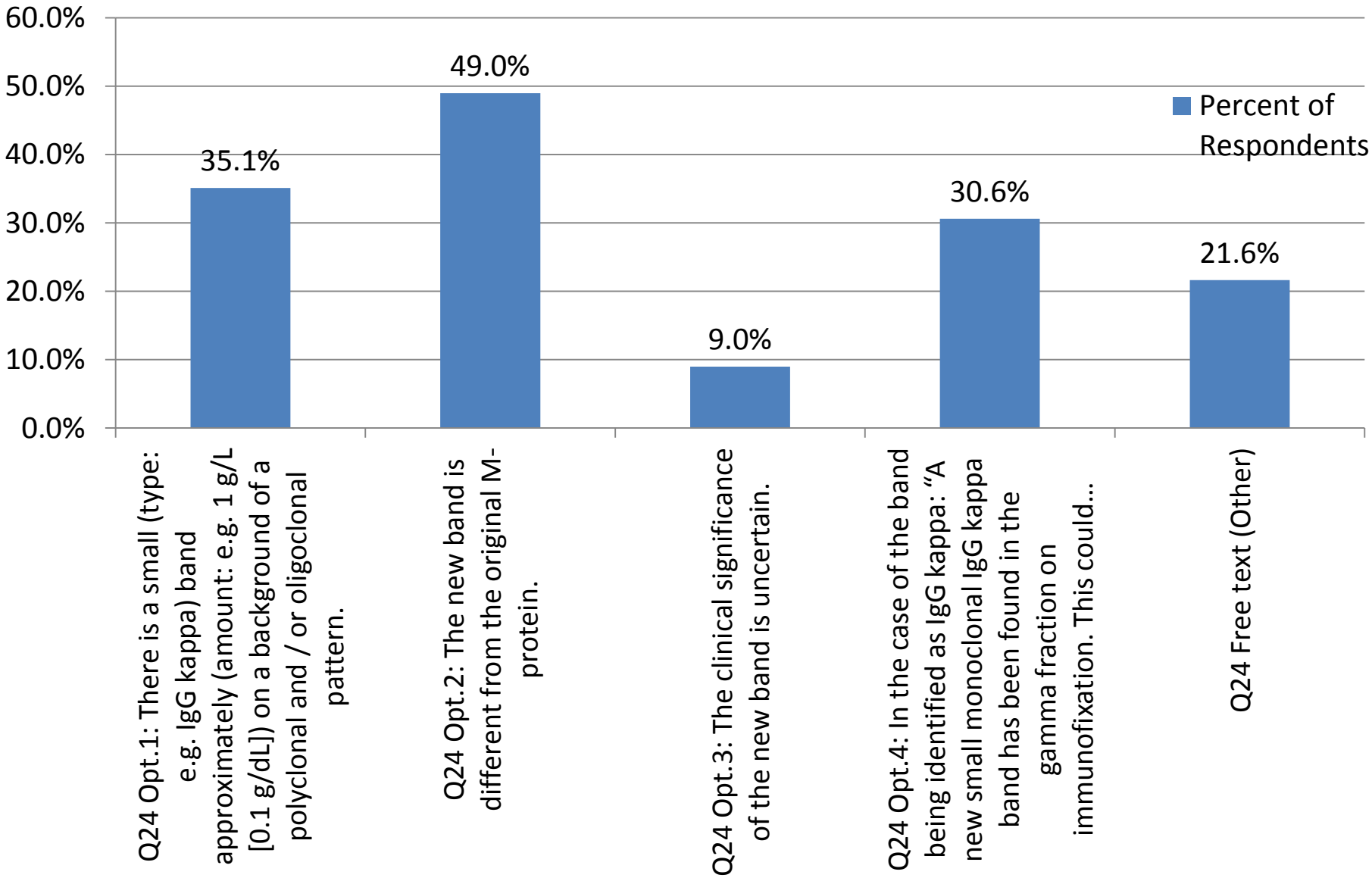
# Q22: How do you report an oligoclonal banding pattern with 2 or more small bands on a polyclonal Ig background on serum protein electrophoresis? Select all that apply.



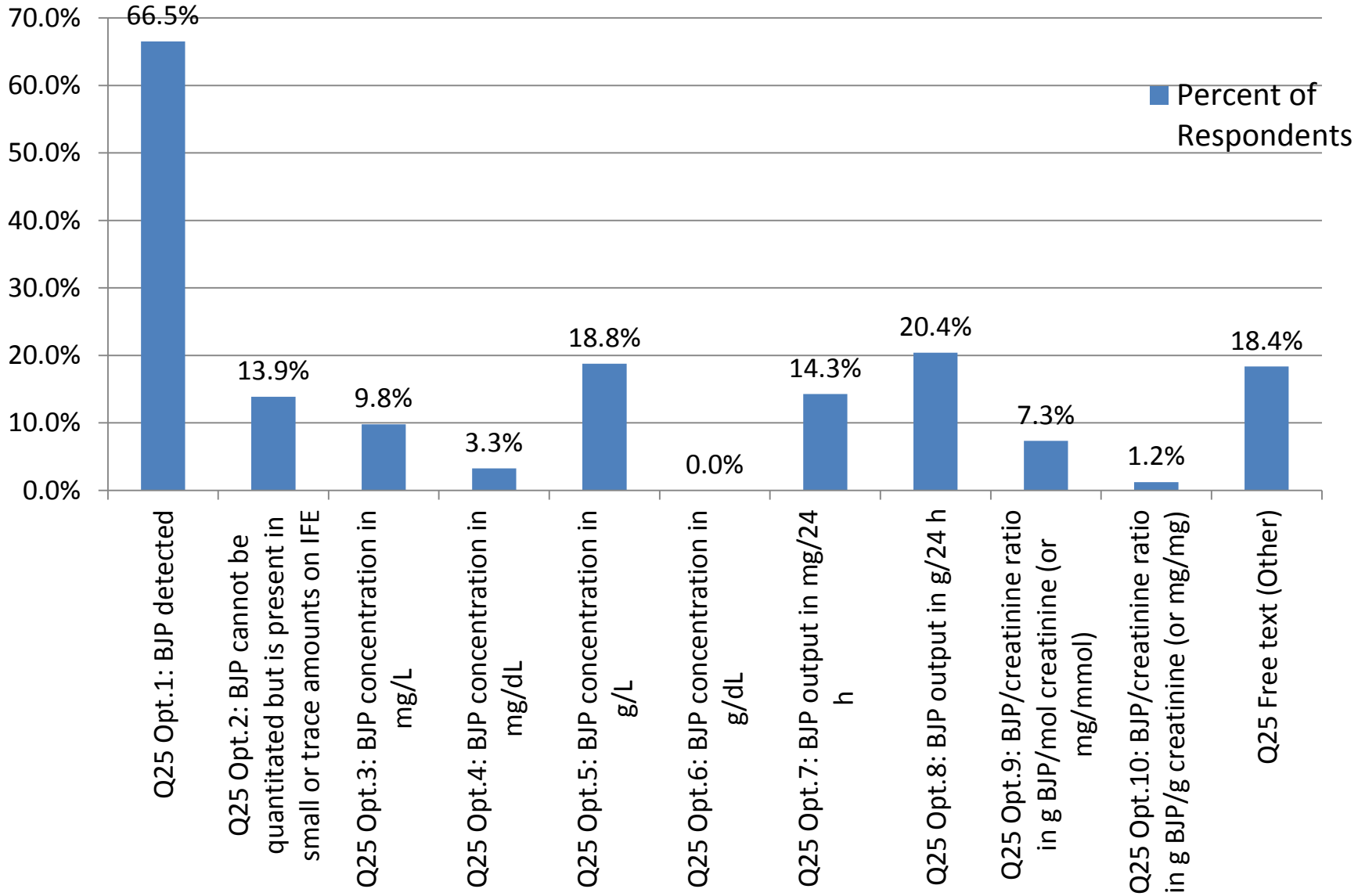
# Q23: How do you report the first presentation of a small abnormal band on serum protein electrophoresis/immunofixation in a patient with no known M-protein? Select all that apply.



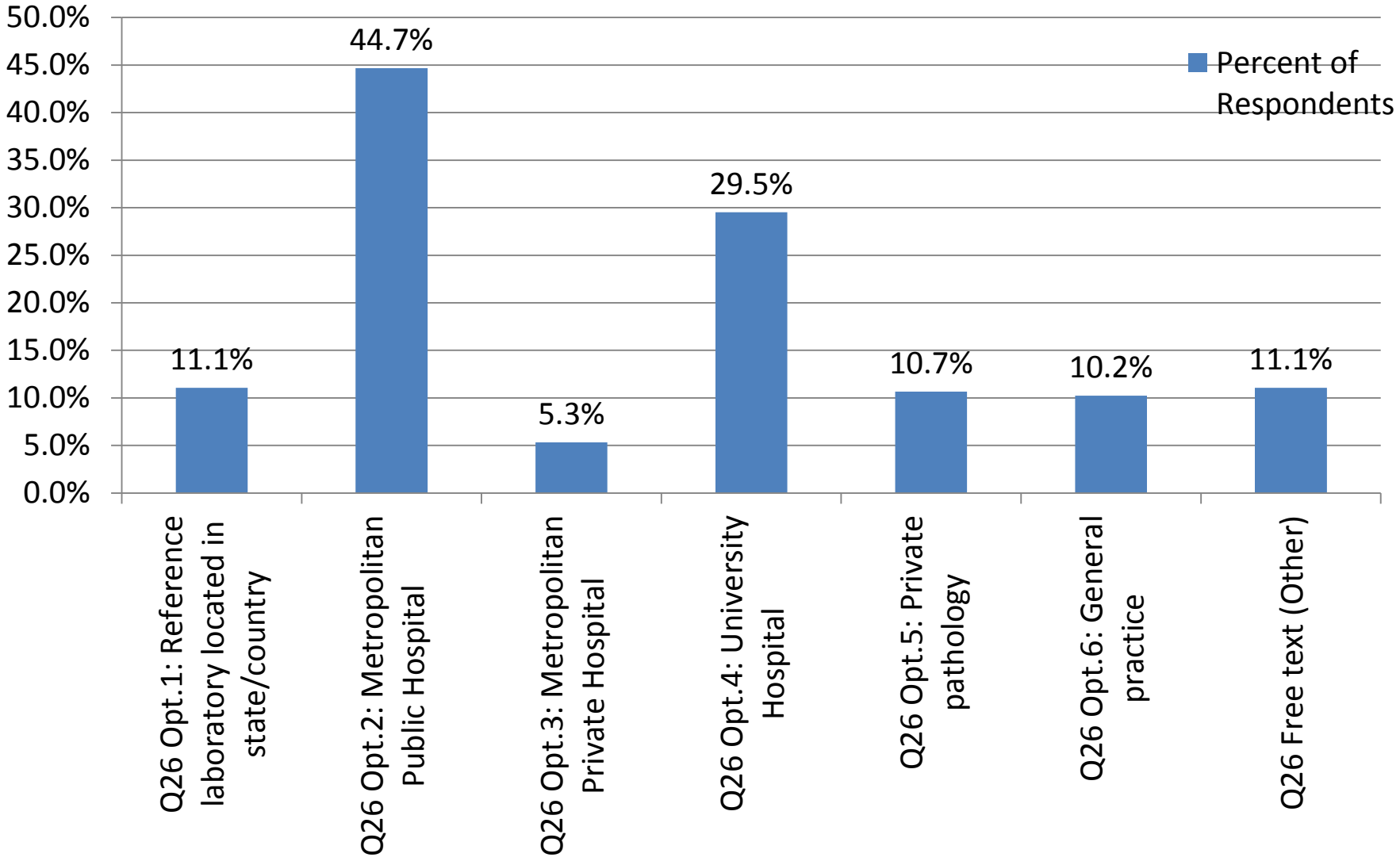
# Q24: How do you report a new, small abnormal band with different electrophoretic mobility from the original M-protein in a patient with a known M-protein? Select all that apply.



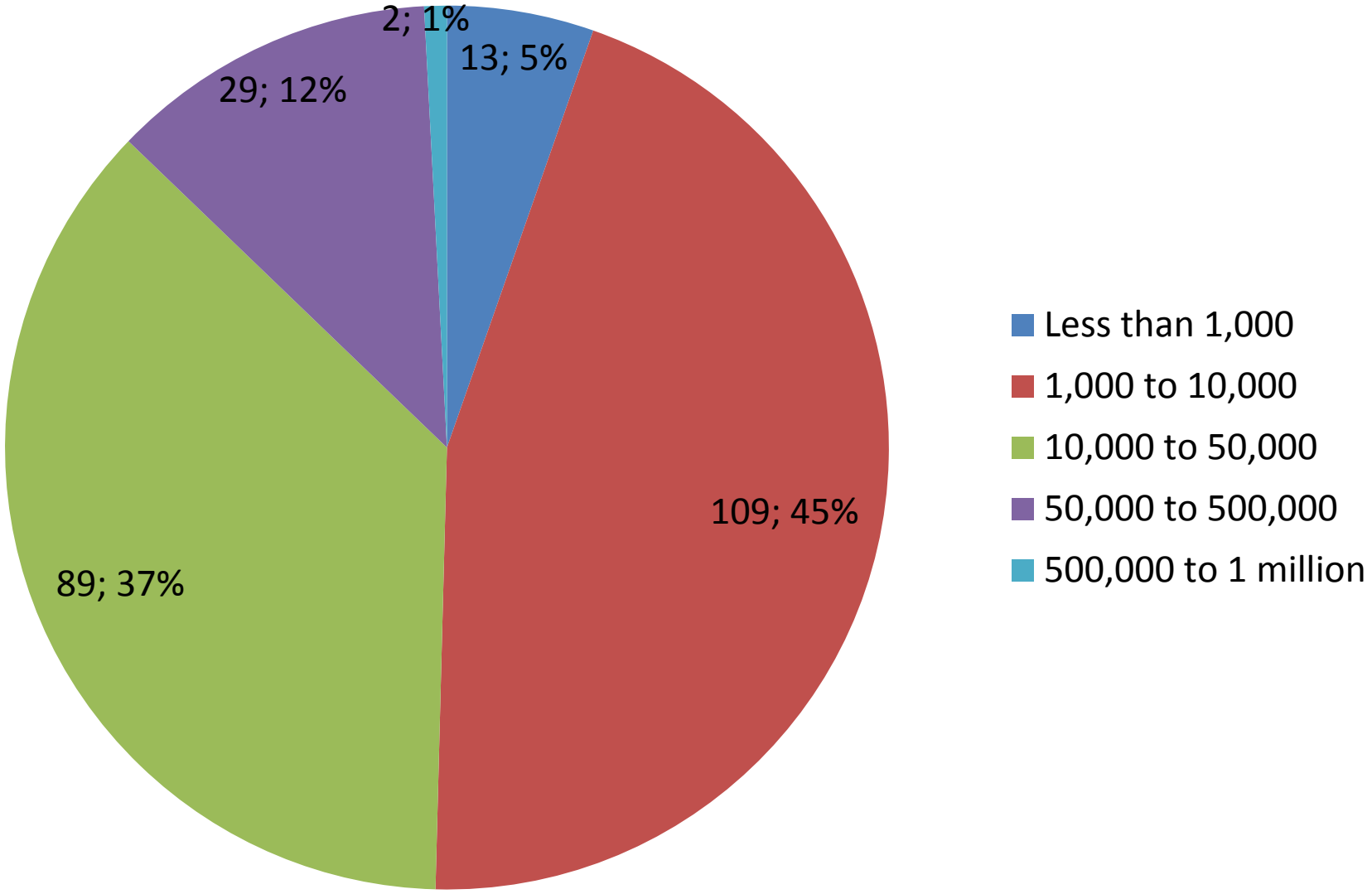
# Q25: How do you report a positive kappa or lambda Bence Jones protein in random and/ or 24 hour urine collections? Select all that apply.



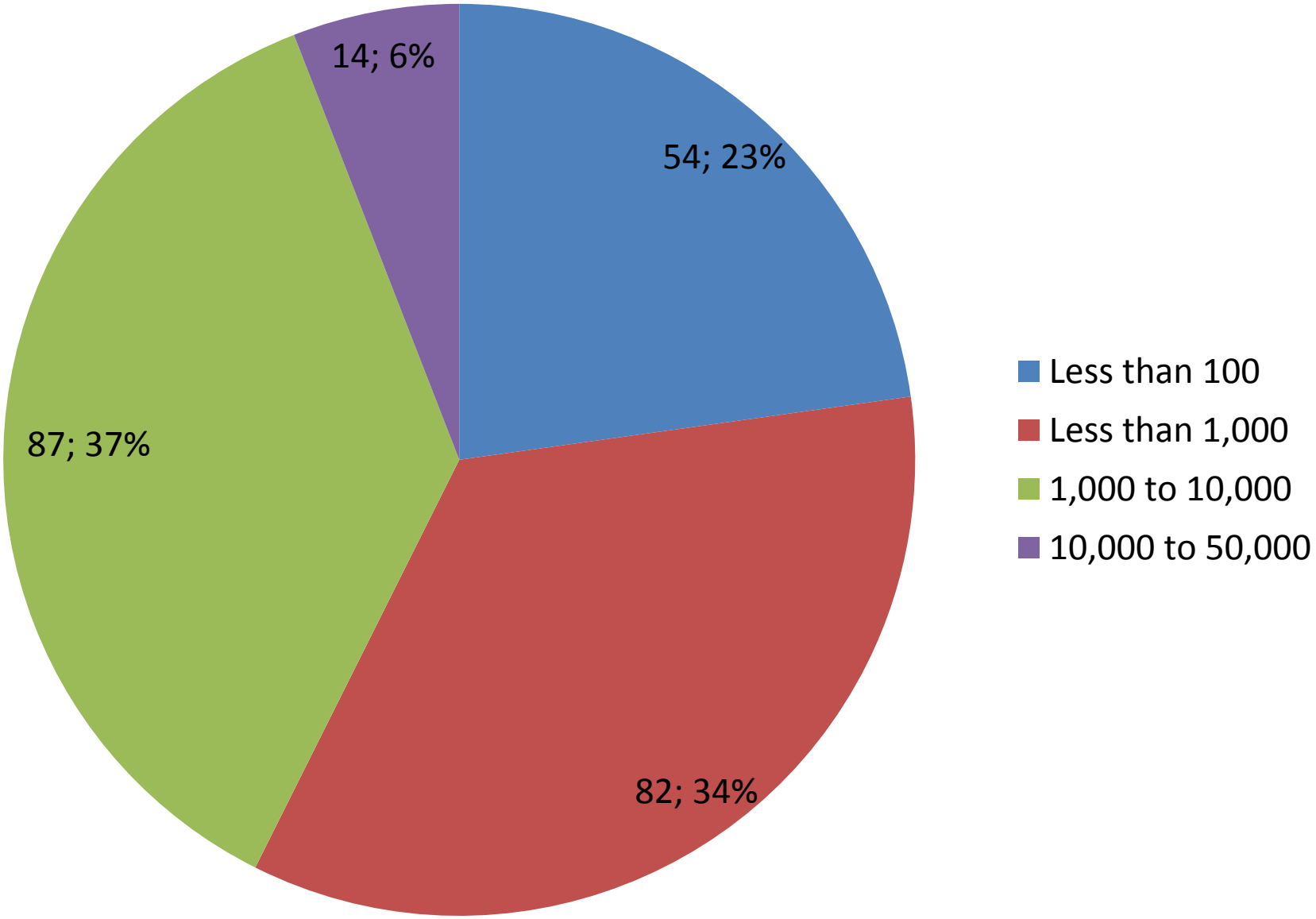
# Q26: Please indicate your laboratory affiliations: Select all that apply.



# Q28: Please indicate your approximate annual volume of SPEP testing



# Q29: Please indicate your approximate annual volume of UPEP testing



# Q30: Please indicate your approximate annual volume of SFLC (by immunoassay) testing