ERNDIM

QUALITY ASSURANCE IN LABORATORY TESTING FOR IEM

2021 Participant Survey Report:

[2020 scheme year]

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1. Introduction

- Participants (804 contacts from 402 centres) were sent the link to the ERNDIM Participant Survey on the Survey Monkey website (www.surveymonkey.com) on 27th January 2021. We asked participants to answer questions relating to the 2020 EQA schemes. The closing date for the survey was 28th February 2021.

2. Summary

- Thank you to everyone who took the time to complete this survey. This report is a summary of all the responses we received. The results from the survey will help us to continue to improve the quality and efficiency of the ERNDIM EQA schemes.
- 45.9% of the laboratories that participated in the 2020 schemes responded to the survey, with the response rate for each of the schemes being between 34.4% - 54.3%.
- The survey has again highlighted areas where we need to improve, such as low sample volume for some schemes, value for money and billing arrangements.
- It is gratifying to see that 96% of respondents rate the quality of products and services we provide as 'excellent' or 'good' and that 68% of respondents believe that the quality of service we offer is getting better. We will continue to make further improvements to our services as we work towards applying for accreditation.
- The issue of sample volume is more difficult. The schemes that use real clinical samples as the EQA materials are dependent on the Scientific Advisors sourcing suitable clinical samples of sufficient volume either by direct contact with clinicians or via donations from participating laboratories. However, we are investigating alternative routes for sample donation. Information on the types of samples that would be useful to ERNDIM can be found on the website (www.erndim.org) under EQA schemes\sample donations. Discounts on scheme fees are also available for some schemes if a donated sample is used as an EQA material. If you would be interested in donating a sample please contact admin@erndim.org for more information.
- For manufactured samples (Quantitative schemes) larger sample volumes are possible, however this would incur additional costs and as such ERNDIM aims to provide sufficient sample volume for most participants while minimising costs. For the majority of schemes, it is possible for participants requiring a larger sample volume to purchase additional sets of samples.
- We are especially pleased that so many of you took the time to complete the survey and to send comments on the schemes. We hope you find the summary where we answer some of your comments (see page 12) and we would welcome any other comments or suggestions for improvements.

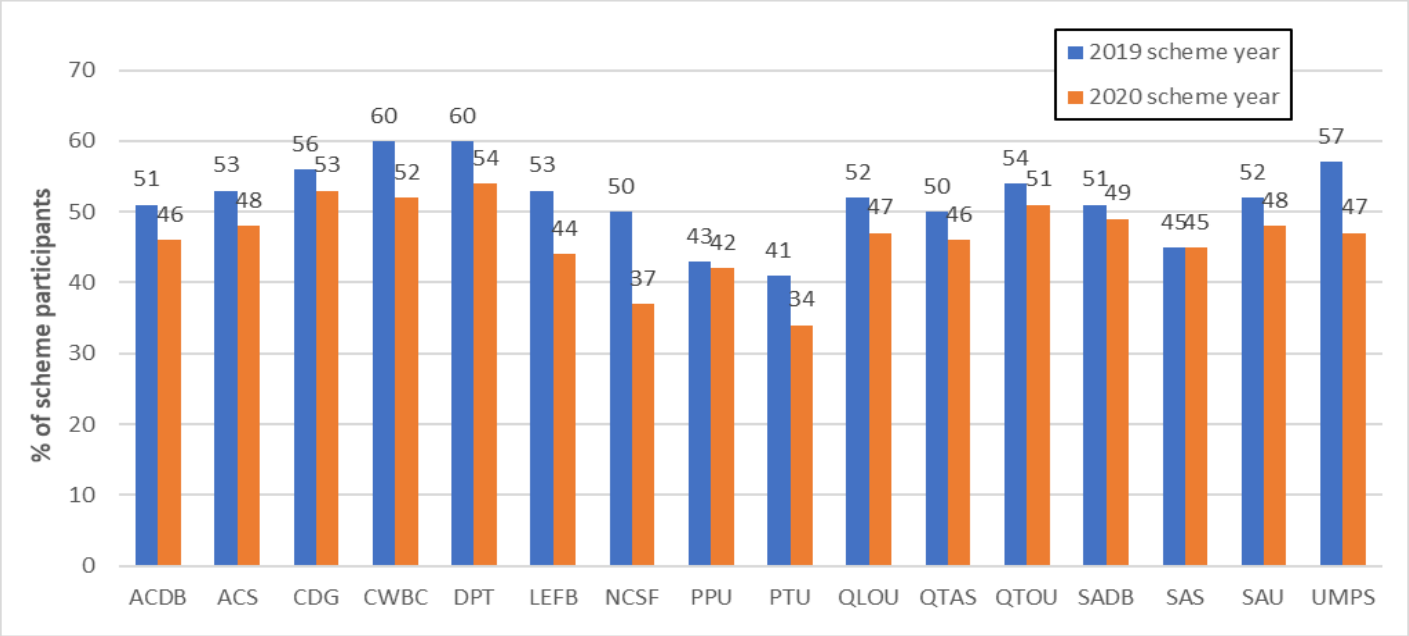
3. Survey Responses

- 196 individuals from 185 centres in 48 countries responded to the survey. The response rate by centre was 46% (compared to 50% in the last survey).

3.1. Please rate the following aspects for each of the ERNDIM quality assurance schemes that you subscribe to (Q.1)

- The response rate for each EQA scheme is shown in Figure 1 and Table 2. For the individual schemes the highest response rate was for DPT (54.3% of 2020 scheme participants) and the lowest was for Neurotransmitter in CSF (34.4% of 2020 scheme participants).
- The response rate was lower for all schemes compared to 2020 with the biggest decrease being seen for Neurotransmitters in CSF (36.8% in 2021 compared to 50.0% in 2020).

Figure 1. Survey responses per EQA scheme (Question 1) as a percentage of the EQA scheme participants *[n.b. 2019 was the first year that the SADB scheme ran as a full EQA scheme]*



Key

EQA Scheme	Code	EQA Scheme	Code
Acylcarnitines in DBS	ACDB	Pterins in urine	PTU
Acylcarnitines in serum	ACS	Qualitative organic acids (urine)	QLOU
Congenital disorders of glycosylation	CDG	Quantitative amino acids (serum)	QTAS
Cystine in white blood cells	CWBC	Quantitative organic acids (urine)	QTOU
Diagnostic Proficiency Testing (urine)	DPT	Special assays - DBS	SADB
Lysosomal storage enzymes (fibroblasts)	LEFB	Special assays - serum	SAS
Neurotransmitters in CSF	NCSF	Special assays - urine	SAU
Purines & pyrimidines (urine)	PPU	Urine Mucopolysaccharides	UMPS

- Participants were asked to rate the following aspects of each scheme:
  - Frequency of samples
  - Appropriateness of analyte concentration
  - Website display
  - Value for money
  - Sample volume
  - Adequacy of the report
  - Usefulness of the annual report
  - Billing arrangements
- Each of the aspects of individual EQA schemes was rated according to the following scoring system:
  1 = Excellent 2 = Good 3 = Poor 4 = Very poor
- The average scores per scheme since 2001 are shown in Table 1 and Figure 2 and scores ≤ 1.5 are highlighted in blue and scores ≥ 2.0 are highlighted in red.
- The overall score for all aspects of all schemes was 1.7, which is the same as in 2020. Eight of the EQA schemes had the same score as last year, four schemes had a worse score than last year (NCSF, PTU, QLOU and QTOU) and 4 schemes had better scores (DPT, LEFB, PPU and SADB).
- The best scoring schemes were DPT, PPU and PTU which scored 1.6. The worst scoring schemes were the CDG and NCSF schemes which both scored 1.9.
- The scores for each scheme in each of the individual aspects are given in Table 2. The score for all 8 of the remained unchanged overall.
- The worst scoring aspects were ‘Sample volume’, ‘Value for money’ and ‘Billing arrangements’ with an average score of 1.8. The best scoring aspects were ‘Frequency of samples’, ‘Adequacy of the report’ and ‘Usefulness of the annual report’ which all scored 1.6.

Table 1. Average scores per scheme (Question 1) *[See Figure 1 for key to scheme codes]*

	Average Scores												
EQA Scheme	**2021**	**2020**	**2019**	**2018**	**2017**	**2016**	**2015**	**2014**	**2013**	**2012**	**2011**	**2007**	**2001**
All schemes	**1.7**	**1.7**	**1.8**	**1.7**	**1.7**	**1.7**	**1.8**	**1.7**	**1.7**	**1.7**	**1.8**	**1.7**	**2.0**
ACDB	1.7	1.7	1.8	1.8	1.8	1.9	1.9	2.0	1.9	1.9	2.0	2.0	-
ACS	1.7	1.7	1.7	1.6	-	-	-	-	-	-	-	-	-
CDG	1.9	1.9	1.9	1.8	1.9	1.9	2.0	2.0	1.9	1.8	1.9	-	-
CWBC	1.7	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.6	1.7	1.6	1.4	-
DPT	1.6	1.7	1.8	1.6	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.7	2.0
LEFB	1.8	1.9	1.8	1.7	1.8	1.9	1.9	2.0	1.9	2.0	2.1	-	-
NCSF	1.9	1.8	1.8	1.9	1.7	-	-	-	-	-	-	-	-
PPU	1.6	1.7	1.7	1.7	1.7	1.8	1.8	1.7	1.7	1.7	1.9	1.6	2.1
PTU	1.6	1.5	1.8	1.9	-	-	-	-	-	-	-	-	-
QLOU	1.7	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.6	1.9
QTAS	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8	1.7	2.0
QTOU	1.8	1.7	1.8	1.7	1.7	1.7	1.8	1.7	1.7	1.7	1.9	1.7	2.1
SADB	1.7	1.8	-	-	-	-	-	-	-	-	-	-	-
SAS	1.7	1.7	1.7	1.7	1.8	1.8	1.7	1.7	1.7	1.7	1.8	1.7	2.0
SAU	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8	2.1
UMPS	1.7	1.7	1.8	1.7	1.8	1.7	1.8	1.8	1.8	1.8	-	-	-

- There were a total of 2 scores of 2.0 or more in this survey: CDG ('Sample volume' = 2.6) and NCSF ('Sample volume' = 2.2).
- The 'Sample volume' score for CDG was again the worst score in the survey (2.6) with a worse score than in 2020 and 2019 (2.4 in 2020 and 2019).
- The best scores of the whole survey (1.4) were for 'Adequacy of the report' for both DPT and QLOU, and 'Usefulness of the Annual Report' for DPT.

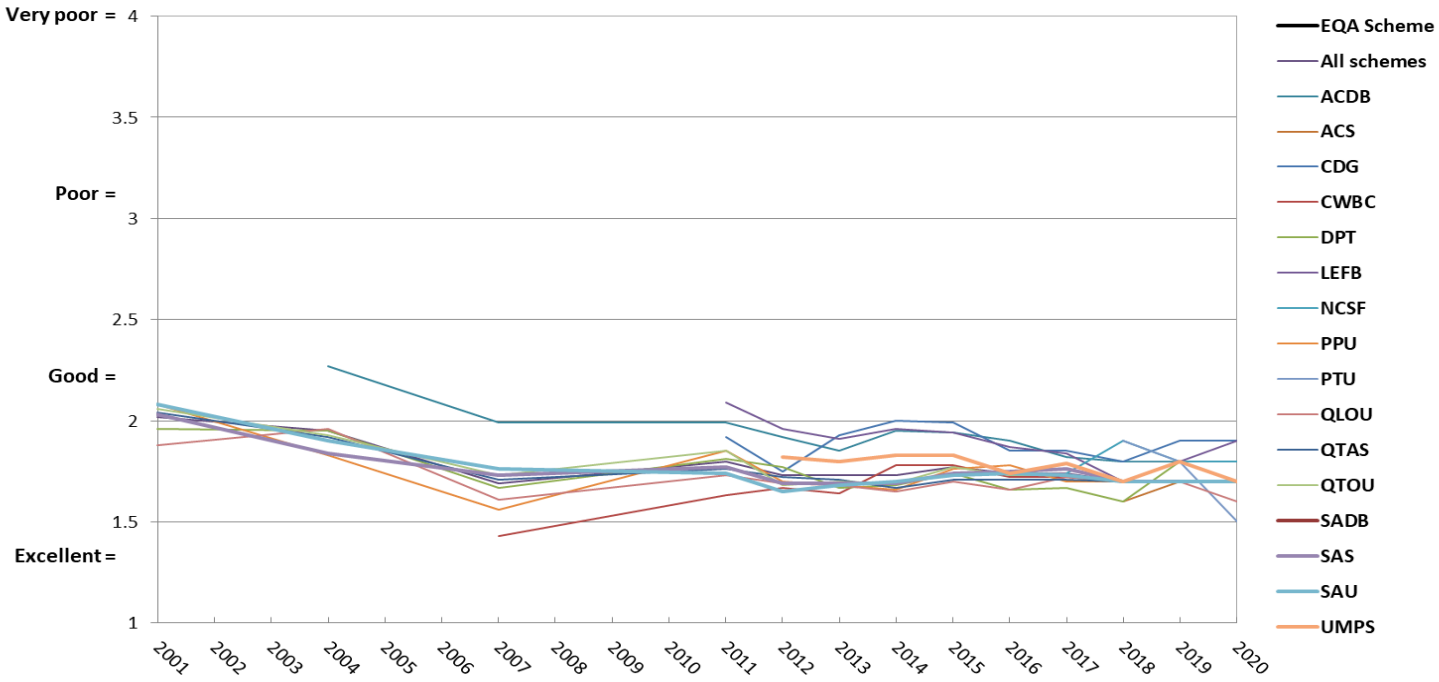


Figure 2. Average score per EQA scheme (Question 1) *[See Figure 1 for key to scheme codes]*

Table 2: Average scores per aspect of each scheme (Question 1) *[See Figure 1 for key to scheme codes]*

Scheme Aspects / EQA Schemes	Frequency of samples	Sample volume	Appropriateness of analyte concentration	Adequacy of the report	Website display	Usefulness of the annual report	Value for money	Billing arrangements	Average per scheme	No. of responses (% of scheme participants)
ACDB	1.8	1.9	-	1.5	1.8	1.5	1.8	1.9	1.7	65 (45.8%)
ACS	1.7	1.6	1.7	1.7	1.8	1.7	1.8	1.8	1.7	64 (49.2%)
CDG	1.6	2.6	-	1.7	1.9	1.7	1.9	1.8	1.9	37 (53.6%)
CWBC	1.7	1.7	1.7	1.6	1.7	1.7	1.8	1.8	1.7	20 (52.6%)
DPT	1.5	1.8	-	1.4	1.6	1.4	1.7	1.8	1.6	57 (54.3%)
LEFB	1.8	1.8	1.8	1.7	1.8	1.7	1.7	1.7	1.8	33 (43.8%)
NCSF	1.7	2.2	1.9	1.7	1.7	1.7	1.9	1.9	1.9	15 (36.8%)
PPU	1.5	1.5	1.6	1.5	1.8	1.6	1.8	1.7	1.6	25 (42.6%)
PTU	1.6	1.8	1.5	1.5	1.5	1.5	1.9	1.8	1.6	12 (34.4%)
QLOU	1.6	1.9	-	1.4	1.7	1.5	1.7	1.7	1.7	113 (48.2%)
QTAS	1.6	1.8	1.6	1.7	1.7	1.6	1.8	1.8	1.7	130 (46.4%)
QTOU	1.7	1.7	1.7	1.7	1.8	1.7	1.9	1.8	1.8	71 (52.3%)
SADB	1.7	1.8	1.7	1.6	1.7	1.6	1.8	1.7	1.7	45 (49.4%)
SAS	1.6	1.6	1.7	1.7	1.7	1.7	1.8	1.8	1.7	109 (46.1%)
SAU	1.6	1.7	1.7	1.6	1.7	1.7	1.9	1.8	1.7	90 (48.6%)
UMPS	1.6	1.9	-	1.6	1.7	1.6	1.8	1.7	1.7	49 (47.4%)
Average for all schemes	**1.6**	**1.8**	**1.7**	**1.6**	**1.7**	**1.6**	**1.8**	**1.8**	**1.7**	**196 (45.9%)**

3.2. Analytes in Quantitative Schemes (Q5 – Q.14)

- A total of 84 individuals (42.9%) made suggestions for analytes to be added to or removed from the Quantitative schemes.
- Where possible we do try to incorporate suggestions for additional analytes but unfortunately this is not always possible. A summary of the suggestions for analytes to added or removed, with some responses from ERNDIM, is below (pages 5 to 8).

Q.5: Acylcarnitines – Serum (14 responses, 11.3% of ACS participants)

Suggested Analytes to be added

Total suggested = 24

Analytes with >1 response

C14	2
C16:1	2
C18:1-OH	2
C22	2
C24	2
C6DC	2
Free carnitine	2
Succinylcarnitine	2

Suggested Analytes to be removed

Total suggested = 3

All Analytes suggested

3-OH-Stearoylcarnitine (C18-OH)	1
C5-OH	1
Total Carnitine	2

ERNDIM Response:

- No analytes were requested by a large number of participants. At this time no further will be added to the scheme as it was agreed by the ERNDIM Scientific Advisory Board (SAB) that it is important to manage the addition of analytes carefully as new additions may affect the stability of the samples due to possible cross reactions.

Q.6: Lysosomal Enzymes (10 responses, 13.7% of LEFB participants)

Suggested Analytes to be added		Suggested Analytes to be removed	
Total suggested = 18		Total suggested = 3	
Analytes with >1 response		**All Analytes suggested**	
Arylsulfatase A	5	Sphingomyelinase	3
arylsulfatase B	4	Alfa-Mannosidase	2

ERNDIM Response:

- The 2019 LEFB scheme saw the first change to the enzymes included for several years. It is the intention of the Scientific Advisor for this scheme to review the performance and requests of participants each year and adjust the scheme to address enzymes which cause difficulty or are of interest to our participants. It is hoped that a wider selection of enzymes will be included in this scheme over several years by rotating some enzymes each year.

Q.7: Neurotransmitters – CSF (3 responses, 7.9% of all NCSF participants)

Suggested Analytes to be added		Suggested Analytes to be removed
Total suggested = 3		Total suggested = 0
Analytes with >1 response		**All Analytes suggested**
MHPG	2	

ERNDIM Response:

- MHPG is currently not requested by sufficient participants to be considered but may be revisited in the future if larger numbers of requests are received.

Q.8: Purines & pyrimidines (6 responses, 11.1% of PPU participants)

Suggested Analytes to be added		Suggested Analytes to be removed	
Total suggested = 3		Total suggested = 1	
Analytes with >1 response		**All Analytes suggested**	
SAICAR	3	Orotidine	1

ERNDIM Response:

- SAICAR is very costly, however this will be reviewed periodically as other changes to the scheme may make this a viable addition in the future.
- Orotidine is a relatively new addition to the scheme, which was requested by a number of participants, it will therefore not be removed at this stage.

Q.9: Pterins – Urine (2 responses, 6.3% of all PTU participants)

Suggested Analytes to be added		Suggested Analytes to be removed
Total suggested = 4		Total suggested = 0
All analytes suggested		**All Analytes suggested**
Dihydrobiopterin	1	
Dihydroneopterin	1	
Sepiapterin	1	
Tetrahydrobiopterin	1	

ERNDIM Response:

- No analytes were requested by a large number of participants.

Q.10: Quantitative amino acids (17 responses, 6.4% of all QTAS participants)

Suggested Analytes to be added		Suggested Analytes to be removed	
Total suggested = 22		Total suggested = 14	
Analytes with >1 response		**Analytes with >1 response**	
Phosphoethanolamine	5	N(pros)-methylhistidine	13
homocystine	2	N(tele)-Methylhistidine	13
		Pipecolic acid	11
		Aspartyl glucosamine	7
		Sulphocysteine	7
		saccharopine	6
		Homocitrulline	5

ERNDIM Response:

- N(pros)-methylhistidine and N(tele)-Methylhistidine will remain in the scheme, while it is understood that these analytes have caused difficulty for some labs the Scientific Advisory board feel it is important that this is addressed rather than removing the analytes.
- Neither analytes suggested for addition to the scheme were requested by a large number of participants. At this time no further will be added to the scheme as it was agreed by the ERNDIM Scientific Advisory Board (SAB) that it is important to manage the addition of analytes carefully as new additions may affect the stability of the samples due to possible cross reactions.

Q.11: Quantitative organic acids (16 responses, 6.4% of all QTOU participants)

Suggested Analytes to be added		Suggested Analytes to be removed	
Total suggested = 33		Total suggested = 4	
Analytes with >1 response		**All Analytes suggested**	
Orotic acid	6	Pyro glutamic acid	1
2-Methyl-3-OH-Butyric acid	5	Suberylglycine	1
homogentisic acid	4	Mevalonic acid	1
3-methylcrotonylglycine	3	Vanillactic acid	1
Proponyl glycine	3		

ERNDIM Response:

- Orotic acid is included in the Special Assays in urine scheme.
- There were not enough requests for addition or removal of any other analyte to justify changes.

Q.12: Special assays – Dried Blood Spots (13 responses, 14.6% of all SADB participants)

Suggested Analytes to be added		Suggested Analytes to be removed	
Total suggested = 27		Total suggested = 3	
Analytes with >2 response		**All Analytes suggested**	
MMA	7	Allo-isoleucine	1
2-OH-Glutaric acid	4	L-Homocysteine	1
methylcitrate	3	NTBC	1

ERNDIM Response:

- MMA is currently included in the Special Assays in Serum scheme.
- Allo-isoleucine and Homocysteine would not be considered for removal, as these are diagnostic metabolites relevant to new-born screening second tier tests and have limited alternative EQA.

Q.13: Special assays – serum (25 responses, 10.5% of all SAS participants)

Suggested Analytes to be added		Suggested Analytes to be removed	
Total suggested = 40		Total suggested = 2	
Analytes with >2 response		**All Analytes suggested**	
aceto acetate	5	carnitine free	1
lanosterol	5	Ketone bodies	1
desmosterol	3		
succinylacetone	3		

ERNDIM Response:

Suggested additions

- Acetoacetate has previously been included in the scheme with some issues.
- ERNDIM may consider inclusion of sterols in a scheme in the future however currently demand is not high enough.
- Succinylacetone will be included for 2022.

Q.14: Special assays – urine (19 responses, 10.7% of all SAU participants)

Suggested Analytes to be added		Suggested Analytes to be removed	
Total suggested = 24		Total suggested = 2	
Analytes with >1 response		**All Analytes suggested**	
AASA	2	succinyl acetone	1
Argininosuccinic acid	2	orotic acid	1
Gb3	2		
Homocystine	2		
porphobilinogen	2		
Total Carnitine	2		

ERNDIM Response:

- The requests for addition of these analytes are too few to provide statistically relevant data if included.
- All analytes suggested for removal are measured and reported by a significant number of participants and therefore would not be removed at this time.

3.3. Do you have any other remarks, comments or suggestions for any of the schemes you subscribed to? (Q.15)

- Number of individual responses = 38 (19.4% of all responses).
- These comments are summarised under 3.14 (page 11) with the comments made in response to Q.26 (see 12).

3.4. Do you think that assessment of interpretation to the Neurotransmitters in CSF scheme adds value to the scheme? (Q.3)

- 26 respondents (65.8% of participants in the NCSF scheme) answered this question.
- The response options were 'It adds a lot of value' (15/26, 57.7%), 'It adds some value' (8/26, 30.8%), 'It makes no noticeable difference' (3/26, 11.5%), 'It detracts some value' (0) or 'It detracts a lot of value' (0).

3.5. Do you think that assessment of interpretation to the Lysosomal Enzymes in fibroblasts scheme adds value to the scheme? (Q.4)

- 38 respondents (52.1% of participants in the LEFB scheme) answered this question.
- The response options were 'It adds a lot of value' (22/38, 57.9%), 'It adds some value' (12/38, 31.6%), 'It makes no noticeable difference' (4/38, 10.5%), 'It detracts some value' (0) or 'It detracts a lot of value' (0).

3.6. Did your laboratory experience much disruption due to the COVID-19 pandemic during 2020? (Q.16)

- 188/196 (95.9%) respondents to the survey answered this question.

Response	Number of respondents
Significant disruption, clinical service affected	16 (8.5%)
Some disruption including to clinical service	55 (29.3%)
Some disruption, clinical service not affected	43 (22.9%)
Minor disruption, clinical service not affected	47 (25.0%)
No disruption	27 (14.4%)

3.7. What types of disruption did your laboratory experience? (Q.17)

- 188/196 (95.9%) respondents to the survey selected at least one option.

Response	Number of respondents
Reduced staffing levels i.e. due to sickness and/or social distancing etc.	131 (66.8%)
Increased workload (including assisting with Covid-19 testing)	48 (24.5%)
Disruption to supply chains	75 (38.3%)
Disruption to external services e.g. servicing/repair of equipment	78 (39.8%)
Issues with delivery of EQA materials	30 (15.3%)

- 7 respondents selected “other” and their replies were:
  - Delayed scheme deadlines.
  - Internal delay in decision making.
  - No disruption other than separating staff into 2 shifts in minimise Covid spread if any outbreak did occur.
  - Temporarily decreased workload (fewer routine samples because of clinic cancellations).
  - We reduce staff as a caution, but we do not have any inconvenience.
  - Sometimes delivery delay.
  - Decreased testing frequency.

3.8. Did your laboratory find the adjustments made by ERNDIM helpful? (Q.18)

Adjustments made by ERNDIM:
- Some scheme submission deadlines were delayed from March/April/May until June 2020.
- Where required, due to difficulties caused by the pandemic, participants were permitted to submit or amend submissions late (within 2 weeks of the submission deadline, prior to publication of results or diagnoses and subject to approval).
- Due to inability to hold face to face meetings as in previous years the DPT workshops were held online.

- 188/196 (95.9%) respondents to the survey answered this question.

Response	Number of respondents
Very helpful	84 (44.7%)
Somewhat helpful	60 (31.9%)
Made no difference	33 (17.6%)
Somewhat unhelpful	10 (5.3%)
Very unhelpful	1 (0.5%)

3.9. Are there any other changes ERNDIM could have made that would have assisted your laboratory with EQA participation during 2020? (Q.19)

- 9/196 (4.6%) respondents entered text into this open text box. Responses were:
  - With hindsight, the delay in submission and reporting led to delay in recognising a calibration issue on one assay, and a problem with reconstitution of ERNDIM EQA material on another.
  - Delaying deadlines did not help us. I was unaware that we could submit or amend submission within two weeks, this may have be publicised more clearly. Can deadlines be synchronised somewhat, it was difficult to keep up to date with changes and as a result we submitted significantly earlier and not in real time. We had insufficient material to repeat.
  - User friendly online schedule of ERNDIM EQAP as well as update to changes in deadlines would help to avoid confusion.
  - Late submissions were helpful but delayed submissions for all schemes until June were too long.

- The adjustments made by erndim were very useful but the fact that several batches were evaluated at once made that some errors were dragged from one batch to another. These errors could have been corrected in the next batch if everything had worked normally
- We would have preferred an interim report with data that could be submitted then a final report once all data submitted. It would allow us to continue to keep an eye on performance.
- The ACDB London scheme could have been better if it was done in time rather than delayed.
- Increase the timeframe in which patient information is available prior to the deadline.
- For us it would have been better if there was a delay in submission for each batch of Erndim. Submission of 4 batches for Organic Acid Test at the same time was not an advantage for us because the method optimization was delayed.

3.10. As we begin 2021 has normal service resumed in your laboratory or are you continuing to experience disruption? (Q.20)

- 188/196 (95.9%) respondents to the survey answered this question.

Response	Number of respondents
Normal service has resumed	70 (38.0%)
There is some ongoing disruption but not affecting clinical service	77 (41.8%)
There is some ongoing disruption that is affecting clinical service	21 (11.4%)
There is a high level of ongoing disruption that is affecting clinical service	2 (1.1%)
not applicable - no disruption experienced at any time	14 (7.6%)

3.11. Does your laboratory use any of the Internal Control Materials provided by MCA laboratories? (Q.21)

- 183/196 (88.3%) respondents answered this question

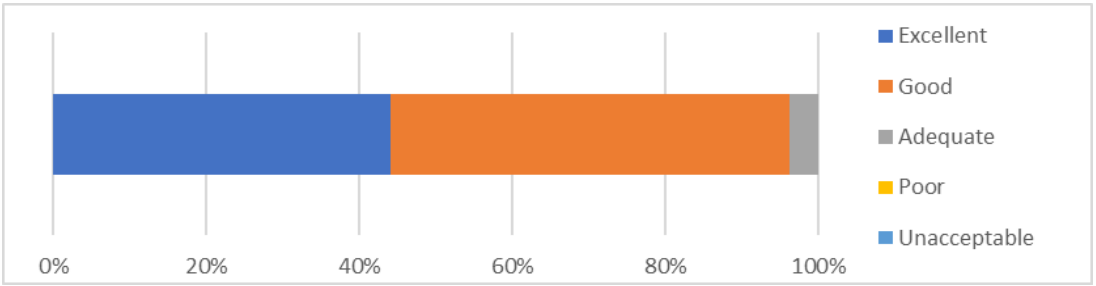
Response	Number of respondents
Yes	79 (43.2%)
No	79 (43.2%)
No, but we may use these in the future	25 (13.7%)

3.12. Comments on the overall performance of ERNDIM (Q.22 – 25)

- The aim of this section is to assess participants' perception of the overall performance of ERNDIM.
- In summary:
  - 95% of respondents rated the quality of services provided by ERNDIM as 'excellent' or 'good'; with 96% of respondents having 'complete' or 'a lot' of confidence that ERNDIM can deliver the service required by participants.
  - 67% of respondents agreed that overall ERNDIM's performance is 'getting better' or 'getting much better'; with 98% of respondents stating that it was 'certain' or 'very likely' that they would use ERNDIM services in the future.

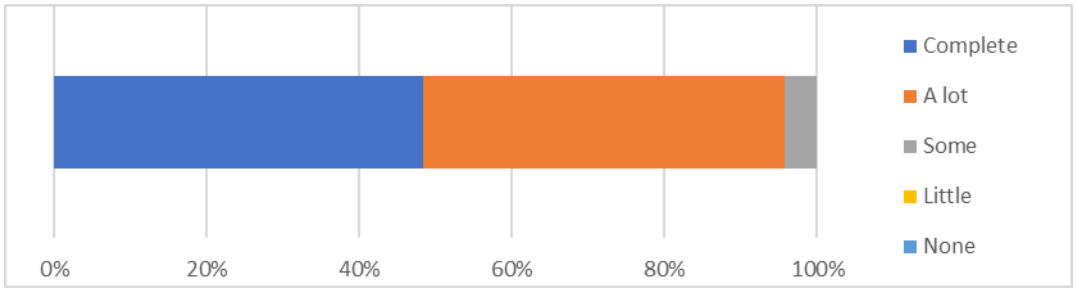
Q.22: Overall, how do you rate the quality of products and services we provide?

(186 individual responses, 94.9% of all responses for this section)



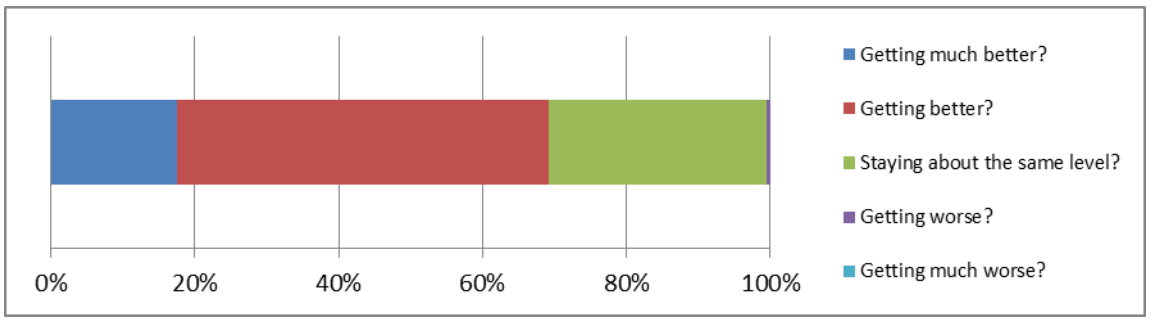
Q.23: What level of confidence do you have in us to deliver the products and services that you require?

(186 individual responses, 94.9% of all responses for this section)



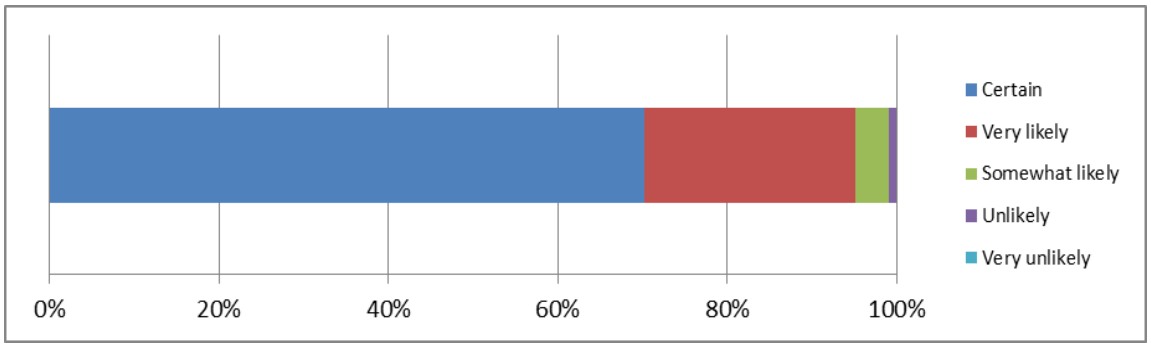
Q.24: Overall, is our performance...

(186 individual responses, 94.9% of all responses for this section)



Q.25: Based on our performance, how likely is it that you will use us in the future?

(186 individual responses, 94.9% of all responses)



3.13. Do you have any other remarks, comments or suggestions for how we could improve the services we provide? (Q.26)

- Number of individual responses = 27 (13.3% of all responses).
- These comments are summarised below with the comments made in response to Q15.

3.14. Summary of Remarks, comments or suggestions for improvements (Q.15 & Q.26)

- Total number of responses was 65 from 49 individuals (= 25% of all responses).
- There were a large number of comments and suggestions for improvement. Below is a summary of some of the most frequent comments with responses from ERNDIM.

Participant Comment	ERNDIM Response
1. Administration	
• A few years ago we submitted a sample for the scheme which was accepted, but we did not receive a discount as the sample had not been used. Each year I query this and this year was informed that the sample had been used and the invoice was incorrect. This seems a rather complex way of dealing with the discount offered to labs who provide a sample for the scheme and relies on someone in the lab remembering that a sample has been sent but not used. It would be easier to offer a discount the year after the sample has been used, regardless of whether it has been used.	• Some samples may not be suitable for use in our EQA schemes, as such we cannot provide a discount until the year following use of the sample in a scheme. We will take your feedback on board and look for ways to improve this process.
• As we bring up new testing we continue to look to ERNDIM to use for proficiency testing. It would be easier to send a document to you listing what we need rather than trying to fit them in boxes in a survey. We are happy you now provide biotinidase and other new analytes. Thank you.	• Unfortunately, it would not be possible for the administration team to handle the data in this way if all participants provided feedback via email.
• In our country by regulation it is established that the documents must be in the language of the country (Spanish) to facilitate reading and understanding, we would like you to evaluate this possibility.	• Although ERNDIM has some Spanish speaking members of the Scientific Advisory Board these are voluntary members who donate their time. Translation of all documents would take a long time.
2. EQA Schemes	
2.1. General	
• Concerning quantitative schemes, could ERNDIM prepare larger volumes in order to keep residual material to sell to labs (for calibration purpose or validation of new methods)?	• Where material is available ERNDIM can provide this to participants following completion of the scheme year or following the submission deadline for the specific sample. Please contact admin@erndim.org or visit the 'participant info' page of the registration website for further details. To prepare a larger amount of 'spare' material would increase scheme participation cost. The number of requests for this material is relatively low so this does not appear to be necessary currently.
• I would be grateful if you could provide support to improve quality, when you see repeated poor performance.	• Poor performance support letters sent to poor performers are aimed to begin a dialogue between participants and Scientific Advisors with the purpose of improving performance. Additionally, the Administration Office can be emailed to make contact with a Scientific Advisor to discuss any performance issues throughout the year.
• I would like to see deadline dates with every data entry for EQA schemes.	• A full EQA scheme submission deadline calendar is available on the ERNDIM website: https://erndim.org/store/docs/DOC4286ERNDIM2021EQAdisp-RAHEKUPA778457-27-05-2021.pdf
2.2. Website reporting	
• In the result entry it can be ensured that the "<" sign is taken into consideration.	• Due to the Quantitative schemes' website statistics requiring absolute values it is not possible for this to be achieved.
• The website for reporting ACDB EQA has to be improved. Most of the time does not open off and on.	• The results submission website will continue to be developed and if you have any specific problems or suggestions for improvements please contact admin@erndim.org. It may be useful to include screenshots of any issues as this may help the website manager to diagnose issues.

Participant Comment	ERNDIM Response
2.3. Acylcarnitines in DBS	
• Acylcarnitines in DBS you have to send a sufficient volume of the sample if something going wrong with the first preparation we will be able to repeat in triplicate the second time preparation .Thank you.	• The Scientific Advisors of this scheme believe that the sample size is suitable. If your process requires additional sample for repeat testing it is possible to order a second set of samples. However, as this scheme uses real patient samples there are limits to the amount that can be provided.
• DBS scheme should be only one scheme for all participant preferably in the middle distance between all participant in Europe.	• Due to the use of real patient samples and the number of participants in this scheme it is not possible to provide enough identical samples for all participants. The introduction of a common sample is being trialled; however, this is dependent upon a large enough bulk sample being available.
2.4. CDG scheme	
• I do understand that sample material is hard to come by but we will be switching to a CZE method after the current round(s) which requires a minimum of approx. 150 uL sample, accounting for dead volume. When we re-register for 2022 it will be by the new method and I am concerned we may struggle to return EQA results due to sample volume.	• The samples provided are from real patient samples, as such there is a limited amount of material. Although we are aware a proportion of participants require a larger volume, the 25ul sample volume provided is sufficient for most participants. It is possible for participants requiring larger volumes to purchase additional material at a discounted fee. Please contact admin@erndim.org for further details.
• The turnaround time for CDG reports is too late for effective actions. It will be better if all the qualitative report will be released at similar time.	• ERNDIM apologises for delays in publications of reports. The CDG scheme scoring is under development and production of interim reports and annual reports is hoped to be automated by the end of 2021. We therefore expect turnaround of reports to improve during 2021 and 2022.
2.5. Cystine in white blood cells	
• Regarding Cystine in White Blood Cells test, and being in mind maybe it is not practicable, the result of this Quality Control it is not comparable to a real sample because it not affected by some problems that could happen during the extraction procedure. To be clear, the most important step int he determination of cystine in WBC is the extraction procedure that in the Quality Controls lack. So, the operators could be very capable for protein determination or cystine test, but not for the extraction procedure. It would be great to think about having a real blood samples to receive in order to check all the procedure and determinations.	• Due to the number of participants, sample size required and distribution of samples it is not possible for real blood samples to be used for this scheme.
2.6. Diagnostic Proficiency Testing	
• Being in the USA, it was wonderfully informative to have the DPT meeting online so we could attend. Should you go back to in person, we'd very much appreciate if an online recording was available in the future.	• The 2020 DPT participant meetings were held online due to cancellation of in person meetings due to Covid-19. The 2021 participant meetings will also be held online and this is something we may consider in the future to facilitate attendance of participants who are otherwise unable to attend the in person events.
2.7. Lysosomal Enzymes in fibroblasts scheme	
• Can we have three (3) cycles for lysosomal enzyme in fibroblasts rather than current 2 cycle with 3 samples per cycle. Separating the samples into 3 cycles will assist in troubleshooting should one needed.	• This scheme previously consisted of 3 submission deadlines with a change to 2 submission deadlines for the 2019 scheme year onwards. We will continue to monitor feedback and if enough participants request a change to 3 submission deadlines this may be reintroduced.
• Please include an option to in the lysosomal enzymes in fibroblasts scheme to say "no deficiency of the enzymes tested" as not all labs test all enzymes included in the EQA scheme and are marked negatively for missing a diagnosis they had not tested for.	• The list of possible diagnoses for this scheme includes 'no obvious enzyme deficiency' as an option. If the enzyme(s) with abnormal activity have not been assayed by the participant this is taken into account when this scheme is scored by the Scientific Advisor.

Participant Comment	ERNDIM Response
2.8. Qualitative Organic Acids	
• Qualitative organic acid volume is too low: useful minimum 2ml	• This scheme aims to provide 2-3ml of sample. Occasionally this may not be possible due to availability of real patient samples, however in these instances the concentration is usually adequate to allow dilution of the sample if volume is not sufficient.
2.9. Quantitative Amino Acids	
• I would appreciate if there is a further detailed explanation in terms of statistical analysis of QTAS. Would be helpful if details related bias is included. Thank you.	• Detailed explanations of the cycle review, analyte reports and annual reports are available on the Quantitative schemes submission website: http://cms.erndimqa.nl/Interactive-Website.aspx .
2.10. Special Assays in DBS	
• Need more blood spots for special assays scheme - we cant test all analytes with sample provided	• The sample size is suitable for most participants, providing a larger sample would require an increase in participation cost. For labs that do require larger sample size it is usually possible to purchase a second set of samples during registration.
2.11. Special Assays in serum	
• For SAS samples, it could be interesting to have different concentrations of NEFA.	• NEFA is present in the sample matrix and is not added as a spiked analyte so it is not possible to vary its concentration in the samples.
• Please include NEFA in the annual report.	• See above. NEFA is recordable for participant information, however as it is not a spiked analyte and does not vary it is not scored for the purpose of performance assessment and for this reason is not included in the annual report.
2.12. Special Assays in urine	
• We would like to ask for larger volume for urine special assay as 5 mls was not adequate.	• A previous survey found that most participants find this sample volume to be adequate. Providing a larger sample volume as standard would result in an increase in participation cost for all participants. However, if your process requires additional sample volume it is usually possible to order a second set of samples.

3.15. Please complete your name and institute address details (Q.27-28)

- Number of individual responses = 120 (61% of all responses).