

MODEL OF QUALITY INDICATORS

Experimental phase


- to define a model of quality indicators
- to standardize the collection of data
- to set desirable quality specifications

Completed

Working phase

- introduction of External Quality Assurance Program to evaluate the performances of clinical laboratories on the basis of the Model of Quality Indicators

MODEL OF QUALITY INDICATORS



Quality Indicator ³	Code	Data to collect ²	Steps	Times	Specification*	Responsibility
Evaluation of appropriateness of the clinical request from general practitioners	QI-1	Number of requests with clinical question / Total number of requests (in percentage)	a) count requests with clinical question and count the total number of requests b) calculate the percentage	A week per month (first week) - per three months (February, April, June)	State-of-the art = Goal =	Nurses/secretaries = collection of data Medical staff = analysis of data and possible actions
	QI-2	Number of appropriate tests (with respect to clinical question) / Number of requests that report clinical question (in percentage)	a) select requests with clinical question and count the required test (total n. of tests) b) analyse clinical question, identify the appropriate tests and count the appropriate tests (n. of appropriate tests) c) calculate the percentage	A week per month (first week) - per three months (February, April, June)	State-of-the art = Goal =	Nurses/secretaries = collection of data Medical staff = analysis of data and possible actions
Evaluation of conformity of the clinical request from general practitioners	QI-3	Number of requests without physician identification / Total number of requests (in percentage)	a) count requests without physician identification and count the total number of requests b) calculate the percentage	A week per month	State-of-the art = Goal =	Nurses/secretaries
	QI-4	Number of unintelligible requests/ Total number of requests (in percentage)	a) count unintelligible requests and count the total number of requests b) calculate the percentage	A week per month	State-of-the art = Goal =	Nurses/secretaries
Evaluation of procedure application: input of request	QI-5	Number of requests with errors concerning patient identification/ total number of requests (percentage)	a) count requests with errors in patient identification and count the total number of requests b) calculate the percentage	A week per month	State-of-the art = Goal =	Nurses/secretaries
	QI-6	Number of requests with errors concerning physician	a) count requests with errors in physician identification and count the total	A week per month	State-of-the art =	Nurses/secretaries

Quality Indicators in Laboratory Medicine: from theory to practice

Preliminary data from the IFCC Working Group Project “Laboratory Errors and Patient Safety”

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Table 1 Quality indicators of the pre-analytical phase.

a) Test ordering	
QI-1	Percentage of "Number of requests with clinical question from general practitioners/Total number of requests from general practitioners"
QI-2	Percentage of "Number of appropriate requests, with respect of clinical question from general practitioners/Number of requests that reports clinical question from general practitioners"
b) Formulation and input of request	
QI-3	Percentage of "Number of requests without physician identification/Total number of requests"
QI-4	Percentage of "Number of unintelligible requests/Total number of requests"
QI-5	Percentage of "Number of requests with errors concerning patient identification/Total number of requests"
QI-6	Percentage of "Number of requests with errors concerning physician identification/Total number of requests"
QI-7a	Percentage of "Number of requests with errors concerning input of tests (missing)/Total number of requests"
QI-7b	Percentage of "Number of requests with errors concerning input of tests (added)/Total number of requests"
QI-7c	Percentage of "Number of requests with errors concerning input of tests (misinterpreted)/Total number of requests"
c) Identification, collection, handling and transport of samples	
QI-8	Percentage of "Number of samples lost-not received/Total number of samples"
QI-9	Percentage of "Number of samples collected in inappropriate container/Total number of samples"
QI-10a	Percentage of "Number of samples hemolyzed (hematology)/Total number of samples"
QI-10b	Percentage of "Number of samples hemolyzed (chemistry)/Total number of samples"
QI-11a	Percentage of "Number of samples clotted (hematology)/Total number of samples with anticoagulant"
QI-11b	Percentage of "Number of samples clotted (chemistry)/Total number of samples with anticoagulant"
QI-12	Percentage of "Number of samples with insufficient sample volume/Total number of samples"
QI-13	Percentage of "Number of samples with inadequate sample-anticoagulant/Total number of samples with anticoagulant"
QI-14	Percentage of "Number of samples damaged in transport/Total number of samples"
QI-15	Percentage of "Number of samples improperly labelled/Total number of samples"
QI-16	Percentage of "Number of samples improperly stored/Total number of samples"

Table 4 Pre-analytical phase: results obtained by laboratories and calculation of quality specifications on the basis of defined criteria (a: median +25%; b: highest value).

QI	No. lab	Range	Median	Mean	Calculation of Quality Specifications and laboratories number within the performance category									
					Optimum		Desirable		Minimum		Unacceptable		Criterion	
					QS	No. lab	QS	No. lab	QS	No. lab	QS	No. lab		
Tests ordering														
QI-1, %	6	9–87	40	41	> 50	3	40–50		30–40	3	< 30		a	
					> 87	1	58–87	1	29–58	1	< 29	3	b	
QI-2, %	4	16–97	69	63	> 86	1	69–86	2	52–69		< 52	1	a	
					> 97	1	65–97	2	32–65	1	< 32		b	
Formulation and input of request														
QI-3, %	9	0–55.7	6.2	11.7	< 4.5	5	4.5–6.2		6.2–7.7	1	> 7.7	3	a	
					< 18.6	7	18.6–37.1	1	37.1–55.7		> 55.7	1	b	
QI-4, %	6	0–21.4	0.25	4.1	< 0.19	2	0.19–0.25	2	0.25–0.31		> 0.31	2	a	
					< 7.1	5	7.1–14.3		14.3–21.4		> 21.4	1	b	
QI-5, %	8	0–10.5	0.5	1.8	< 0.4	4	0.4–0.5		0.5–0.6		> 0.6	4	a	
					< 3.5	7	3.5–7.0		7.0–10.5	1	> 10.5		b	
QI-6, %	6	0–6.2	0.08	1.6	< 0.06	3	0.06–0.08		0.08–0.11		> 0.11	3	a	
					< 2.1	4	2.1–4.1	1	4.1–6.2	1	> 6.2		b	
QI-7a, %	7	0–14.6	0.4	2.6	< 0.3	3	0.3–0.4	1	0.4–0.5		> 0.5	3	a	
					< 4.9	6	4.9–9.7		9.7–14.6		> 14.6	1	b	
QI-7b, %	5	0–0.13 (+53.3) ^a	0.05	0.06	< 0.04	2	0.04–0.05	1	0.05–0.06		> 0.06	2	a	
					< 0.04	2	0.04–0.08	1	0.08–0.13		> 0.13	2	b	
QI-7c, %	6	0–17	0.23	3.0	< 0.17	3	0.17–0.23		0.23–0.29		> 0.29	3	a	
					< 6.0	5	6.0–11.0		11.0–17.0		> 17.0	1	b	
Identification, collection, handling and transport of samples														
QI-8, %	8	0.004–0.63	0.1	0.19	< 0.075	4	0.075–0.1		0.1–0.125		> 0.125	4	a	
					< 0.21	5	0.21–0.42	1	0.42–0.63	2	> 0.63		b	
QI-9, %	9	0–0.2 (+8.8) ^a	0.03	0.05	< 0.02	4	0.02–0.03	1	0.03–0.04	1	> 0.04	3	a	
					< 0.07	6	0.07–0.13	1	0.13–0.20		> 0.20	2	b	
QI-10a, %	3	0.04–0.9	0.4	0.45	< 0.3	1	0.3–0.4	1	0.4–0.5		> 0.5	1	a	
					< 0.3	1	0.3–0.6	1	0.6–0.9		> 0.9	1	b	
QI-10b, %	8	0.3–3.4	1.6	1.8	< 1.2	3	1.2–1.6	1	1.6–2.0	1	> 2.0	3	a	
					< 1.1	3	1.1–2.3	2	2.3–3.4		> 3.4	3	b	
QI-11a, %	6	0.013–1.70	0.35	0.57	< 0.26	2	0.26–0.35	1	0.35–0.44		> 0.44	3	a	
					< 0.6	4	0.6–1.1	1	1.1–1.7	1	> 1.7		b	
QI-11b, %	3	0.031–1.5	0.10	0.54	< 0.075	1	0.075–0.10		0.10–0.125		> 0.125	2	a	
					< 0.5	2	0.5–1.0		1.0–1.5	1	> 1.5		b	
QI-12, %	10	0.012–1.13	0.04	0.2	< 0.03	5	0.03–0.04		0.04–0.05	1	> 0.05	4	a	
					< 0.37	9	0.37–0.76		0.76–1.13		> 1.13	1	b	
QI-13, %	7	0–1.09 (+52.5) ^a	0.27	0.034	< 0.20	2	0.20–0.27	1	0.27–0.33	2	> 0.33	2	a	
					< 0.36	5	0.36–0.73		0.73–1.09	1	> 1.09	1	b	
QI-14, %	7	0–1.02	0.0004	0.027	< 0.0003	3	0.0003–0.0004	2	0.0004–0.0005		> 0.0005	2	a	
					< 0.034	5	0.034–0.068		0.068–1.02	2	> 1.02		b	

Example of Report for participants

IFCC

Working Group on

"Laboratory Errors and Patient Safety"

Model of Quality Indicators

- Preliminary Results -

Quality Indicator		Range	N.
QI-01	Percentage (Number of requests with clinical question from general practitioners / Total number of requests from general practitioners)	4,13 - 87,39	6
QI-02	Percentage (Number of appropriate tests , with respect to clinical question, from general practitioners / Number of requests that report clinical question from general practitioners)	69,2 - 97,27	3
QI-03	Percentage (Number of requests without physician identification / Total number of requests)	0 - 21,09	6
QI-04	Percentage (Number of unintelligible requests/ Total number of requests)	0 - 21,45	6

Example of Report for participants

QI-05	Percentage (Number of requests with errors concerning patient identification/ total number of requests)	0 - 10,54	7
QI-06	Percentage (Number of requests with errors concerning physician identification/ total number of requests)	0 - 6,21	6
QI-07a	Percentage (Number of requests with errors concerning input of tests (missing)/ Total number of requests)	0,09 - 14,54	5
QI-07b	Percentage (Number of requests with errors concerning input of tests (added)/ Total number of requests)	0 - 53,29	5
QI-07c	Percentage (Number of requests with errors concerning input of tests (misinterpreted) / Total number of requests)	0 - 16,98	6
QI-08	Percentage (Number of samples lost-not received/Total number of samples)	0,01 - 0,51	6

Example of Report for participants

QI-08	Percentage (Number of samples lost-not received/Total number of samples)
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ESP001	0,24 (1769 / 751362)
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IRL001	0,03 (102 / 307708)
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ITA001	0,01 (195 / 1650664)
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ITA004	0,51 (2824 / 554741)
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ITA006	0,01 (15 / 140000)
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PLE001	0,04 (25 / 60270)
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QI-09	Percentage (Number of samples collected in inappropriate container/Total number of samples)	0 - 8,84	7
QI-10a	Percentage (Number of samples hemolyzed (haematology)/ Total number of samples)	0,37 - 0,95	2
QI-10b	Percentage (Number of samples hemolyzed (chemistry)/ Total number of samples)	0,38 - 3,42	5
QI-11a	Percentage (Number of samples clotted (haematology)/Total number of samples)	0,02 - 1,69	4
QI-11b	Percentage (Number of samples clotted (chemistry)/Total number of samples)	0,03 - 1,48	3
QI-12	Percentage (Number of samples with insufficient sample volume/ Total number of samples)	0,01 - 1,14	8
QI-13	Percentage (Number of samples with inadequate sample-anticoagulant volume ratio/Total number of samples)	0 - 52,5	6

Example of Report for participants

QI-09 **Percentage (Number of samples collected in inappropriate container/Total number of samples)**

ESP001	0,03	(233 / 751362)
IRL001	8,84	(25017 / 282892)
ITA001	0,001	(3 / 466404)
ITA004	0,03	(155 / 554741)
ITA006	0	(10 / 1038002)
PLE001	0,2	(121 / 60270)
SIN001	0	(0 / 43881)

Quality Specifications

Table 6 Proposed Quality Specifications.

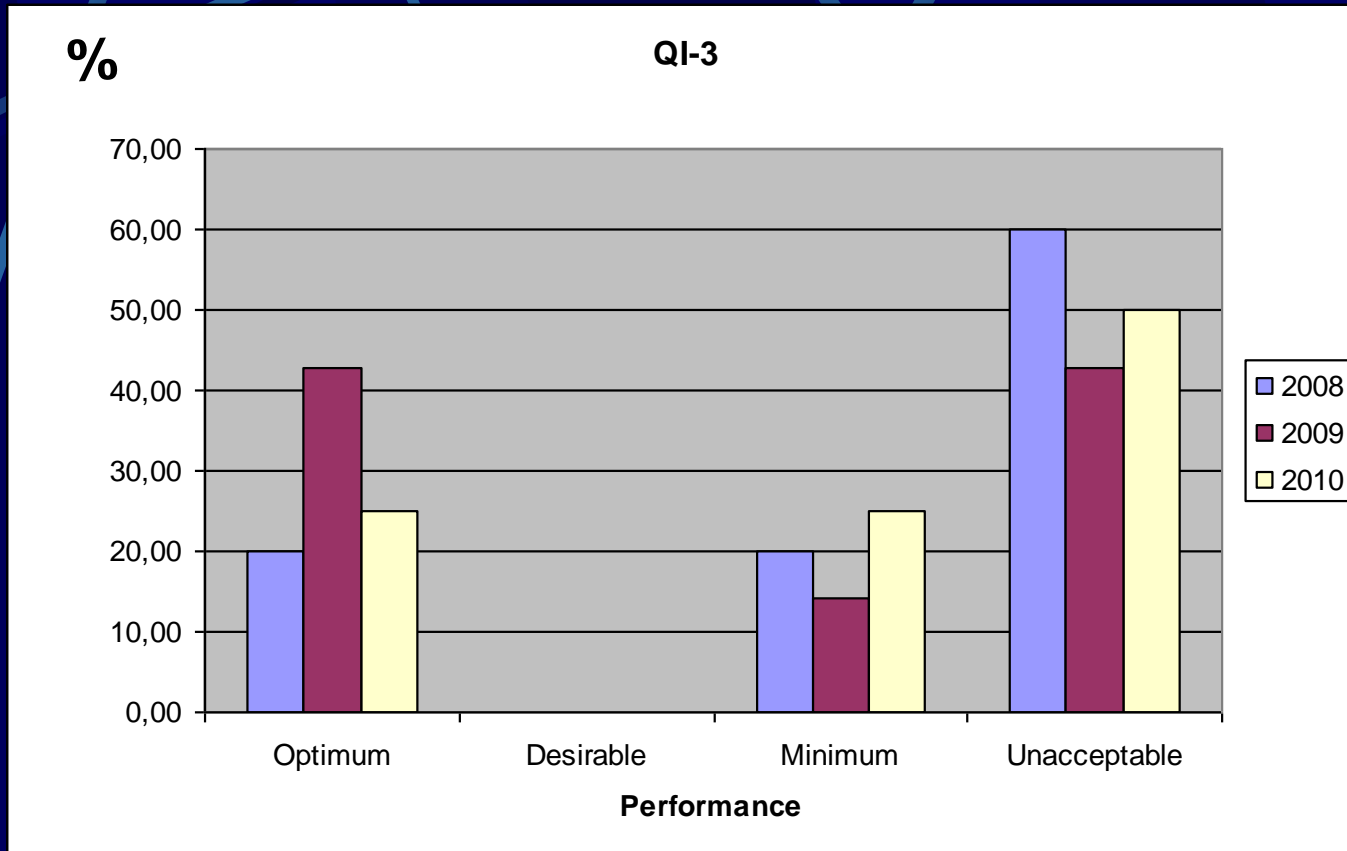
Quality indicators	Quality specifications			
	Performance levels			
	Optimum	Desirable	Minimum	Unacceptable
QI-1, %	> 87	58–87	29–57	< 29
QI-2, %	> 97	65–97	32–64	< 32
QI-3, %	< 5.0	5.0–6.0	6.1–8.0	> 8.0
QI-4, %	< 0.20	0.20–0.25	0.26–0.30	> 0.30
QI-5, %	< 0.40	0.40–0.50	0.51–0.60	> 0.60
QI-6, %		< 0.10		
QI-7a, %	< 0.30	0.30–0.40	0.41–0.50	> 0.50
QI-7b, %		< 0.1		
QI-7c, %	< 0.20	0.20–0.25	0.26–0.30	> 0.30
QI-8, %	< 0.20	0.20–0.40	0.41–0.60	> 0.60
QI-9, %	< 0.07	0.07–1.13	1.14–0.20	> 0.20
QI-10a, %			N/A	
QI-10b, %	< 1.0	1.0–1.5	1.6–2.0	> 2.0
QI-11a, %	< 0.50	0.50–1.0	1.1–2.0	> 2.1
QI-11b, %			N/A	
QI-12, %	< 0.40	0.40–0.80	0.81–1.20	> 1.20
QI-13, %	< 0.20	0.20–0.30	0.31–0.40	> 0.40
QI-14, %		< 0.1		
QI-15, %	< 0.07	0.07–0.15	0.16–0.20	> 0.20
QI-16, %		< 0.1		
QI-17, %	< 1.5	1.5–3.0	3.1–5.0	> 5.0
QI-18, %			N/A	
QI-19, %			N/A	
QI-20, %			N/A	
QI-21, %	< 0.4	0.4–0.5	0.6–0.7	> 0.7
QI-22, %	> 96	77–96	58–76	< 58
QI-23, min	< 50	50–100	101–160	> 160
QI-24, %			N/A	
QI-25, number			N/A	

PRE-ANALYTICAL PHASES

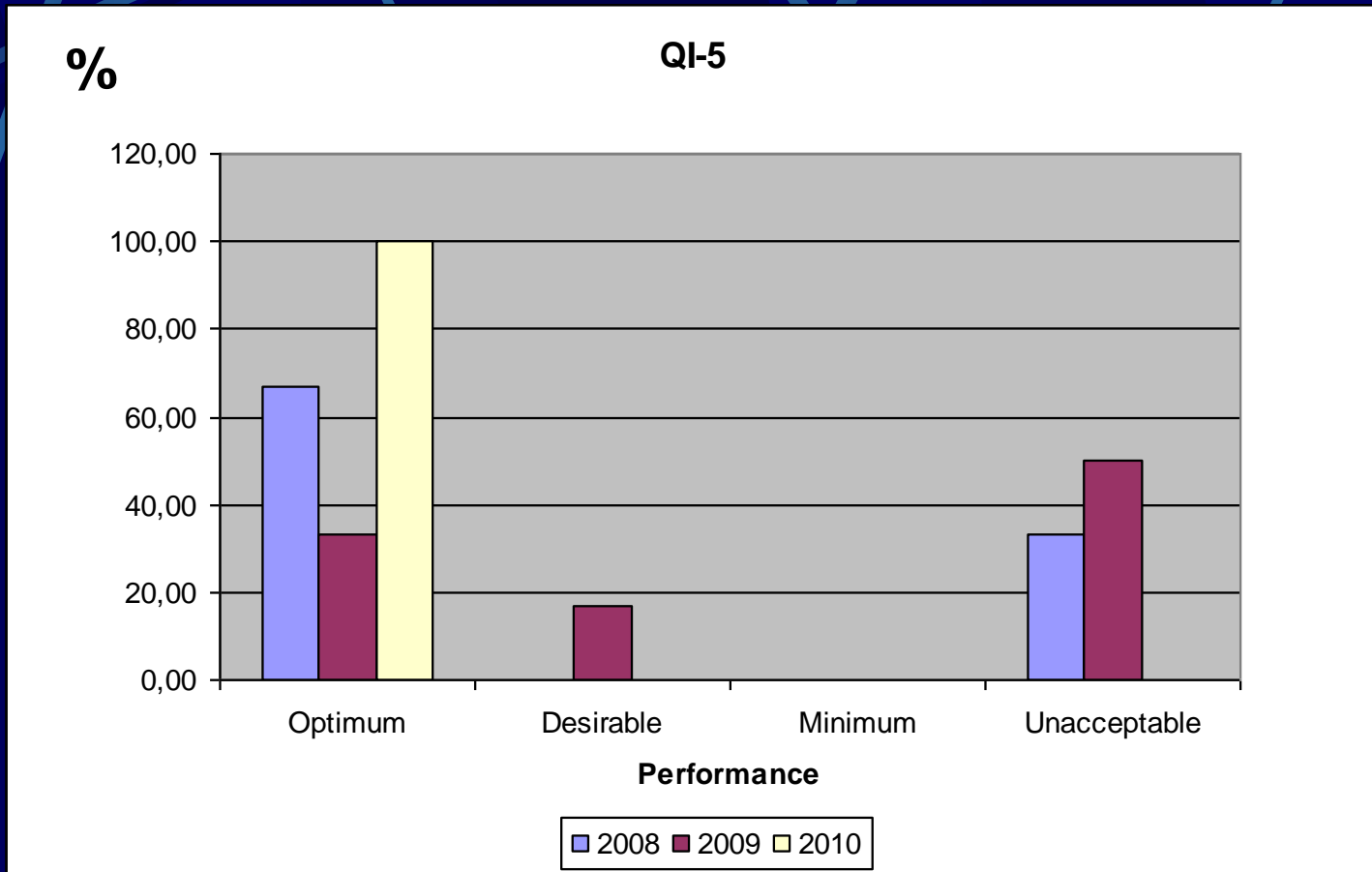
Performances of participating laboratories
in the last three years?



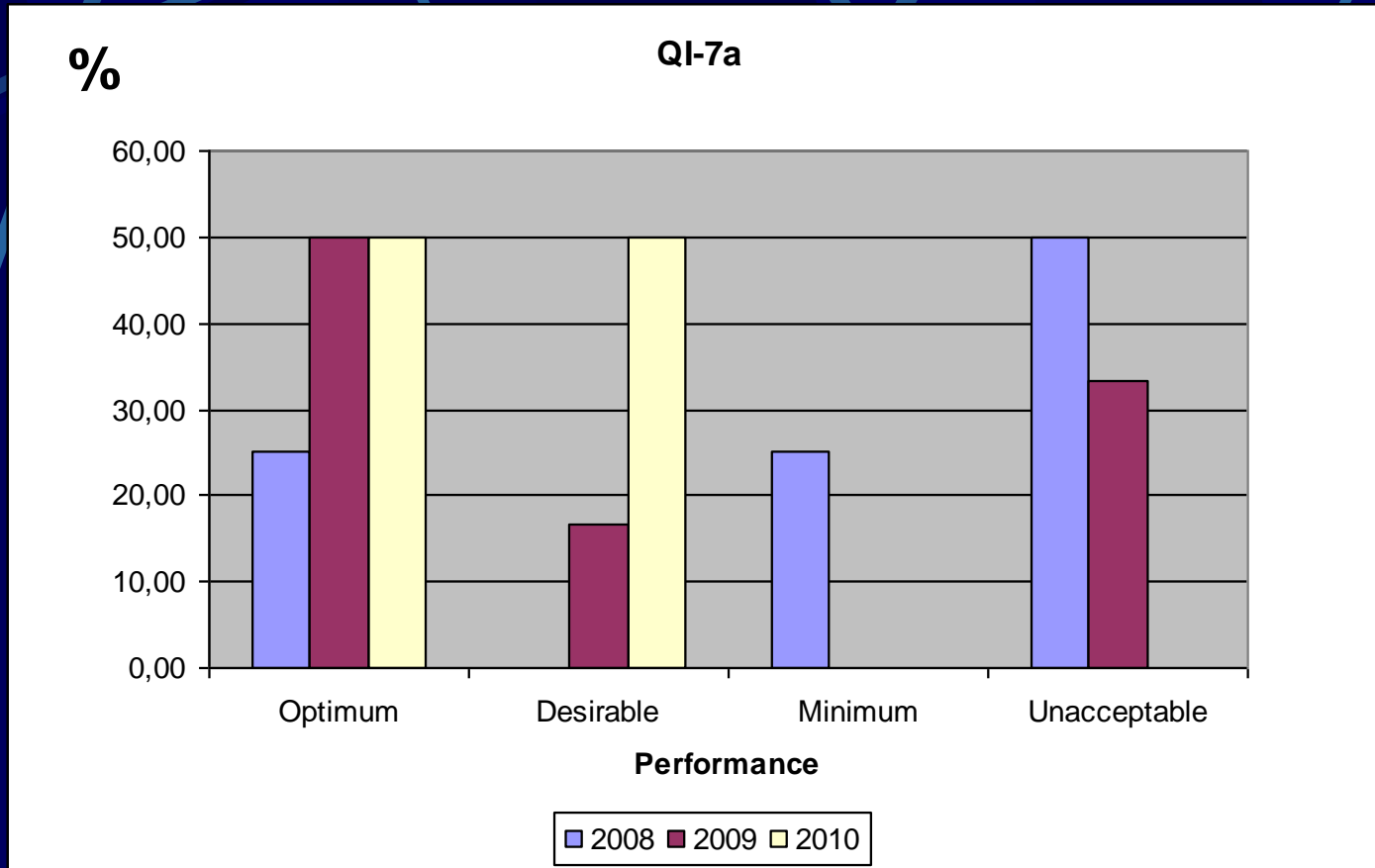
Percentage (Number of requests without physician identification / Total number of requests)



Percentage (Number of requests with errors concerning patient identification/ total number of requests)



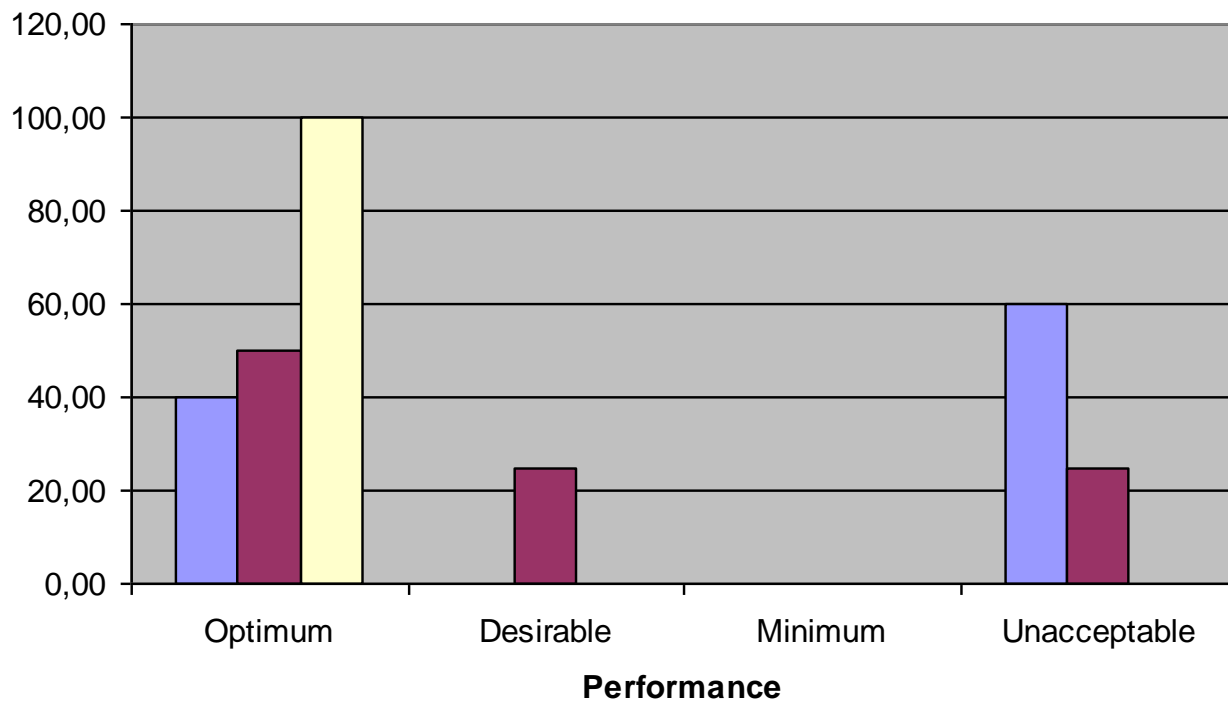
Percentage (Number of requests with errors concerning input of tests (missing)/ Total number of requests)



Percentage (Number of requests with errors concerning input of tests (misinterpreted) / Total number of requests)

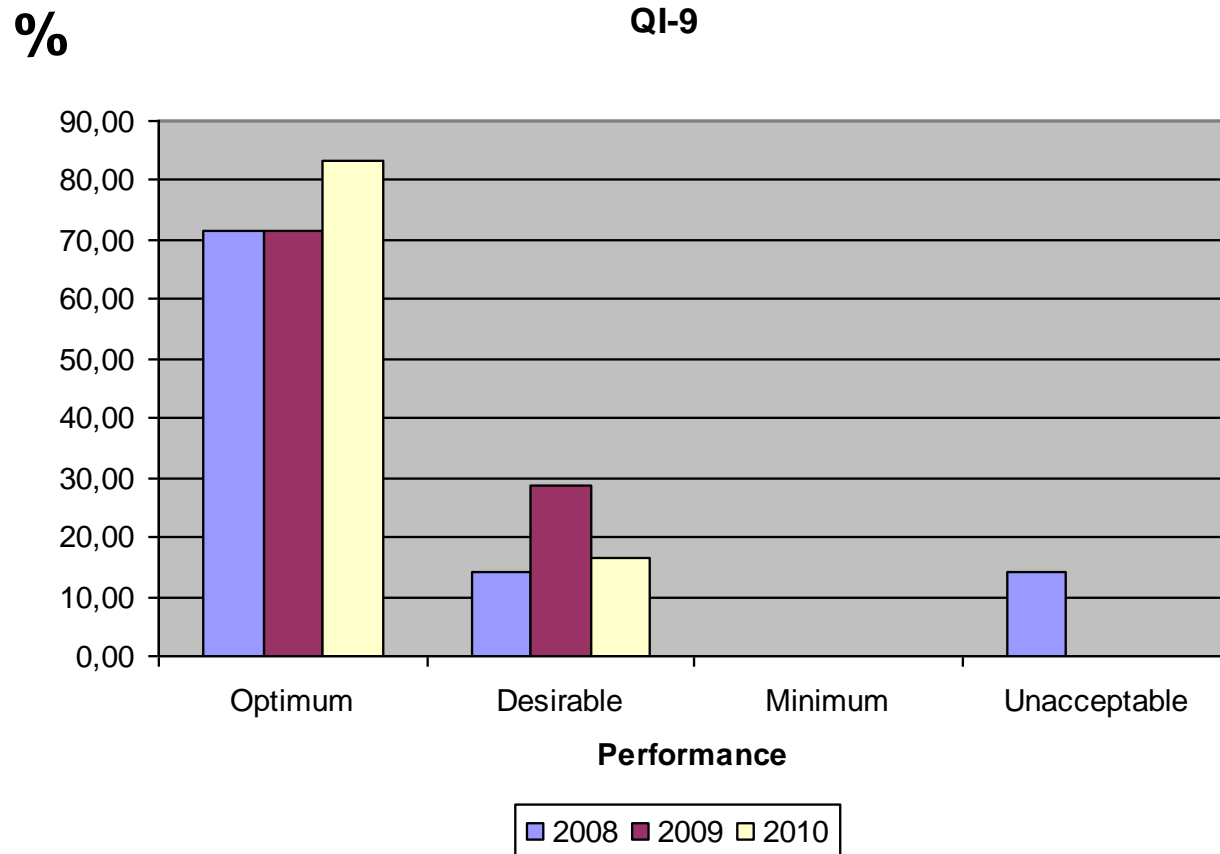
%

QI-7c



2008 2009 2010

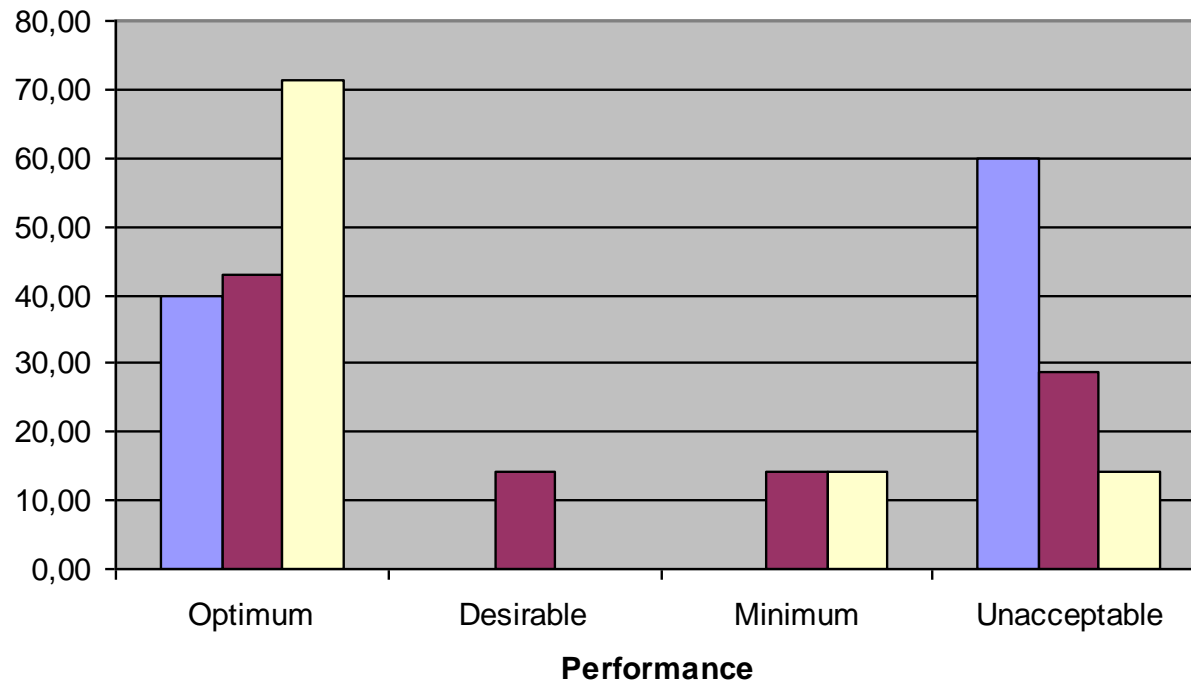
Percentage (Number of samples collected in inappropriate container/Total number of samples)



Percentage (Number of samples hemolyzed
(chemistry)/ Total number of samples)

%

QI-10b

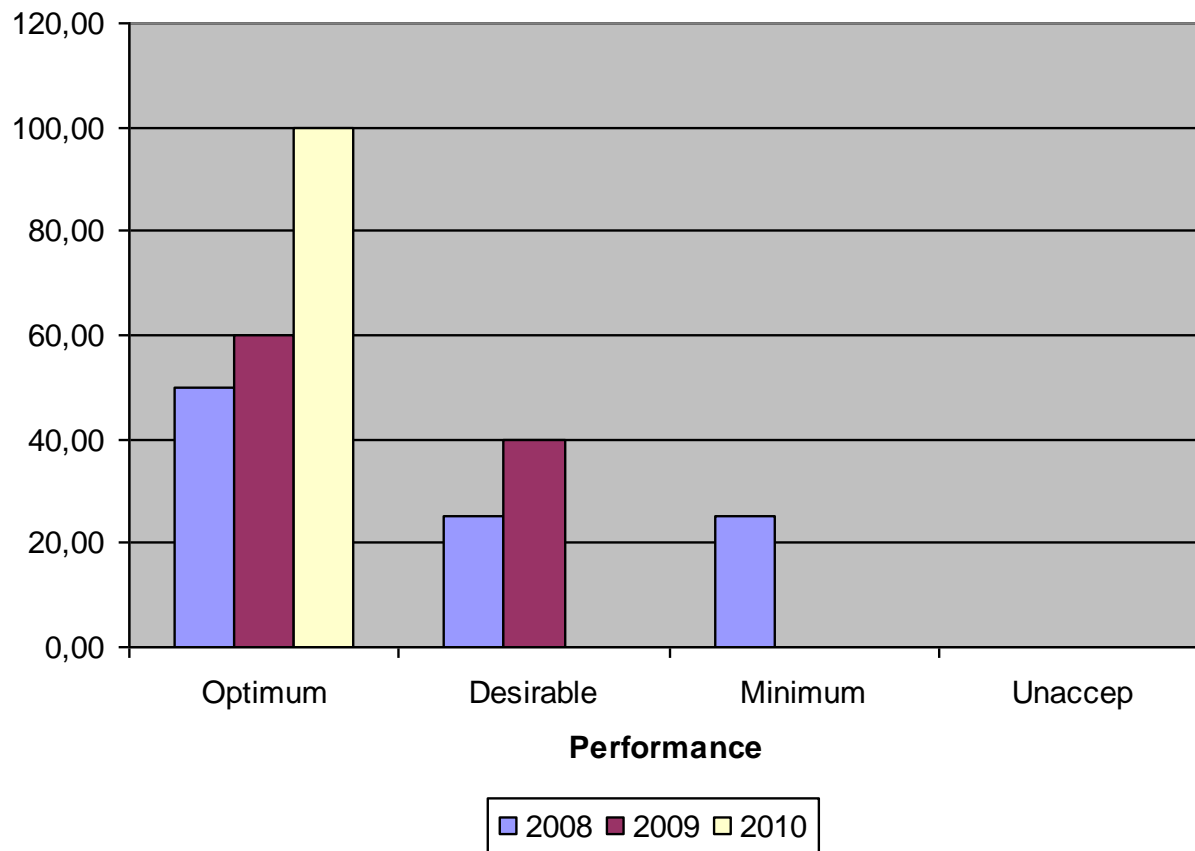


2008 2009 2010

Percentage (Number of samples clotted
(haematology)/Total number of samples)

%

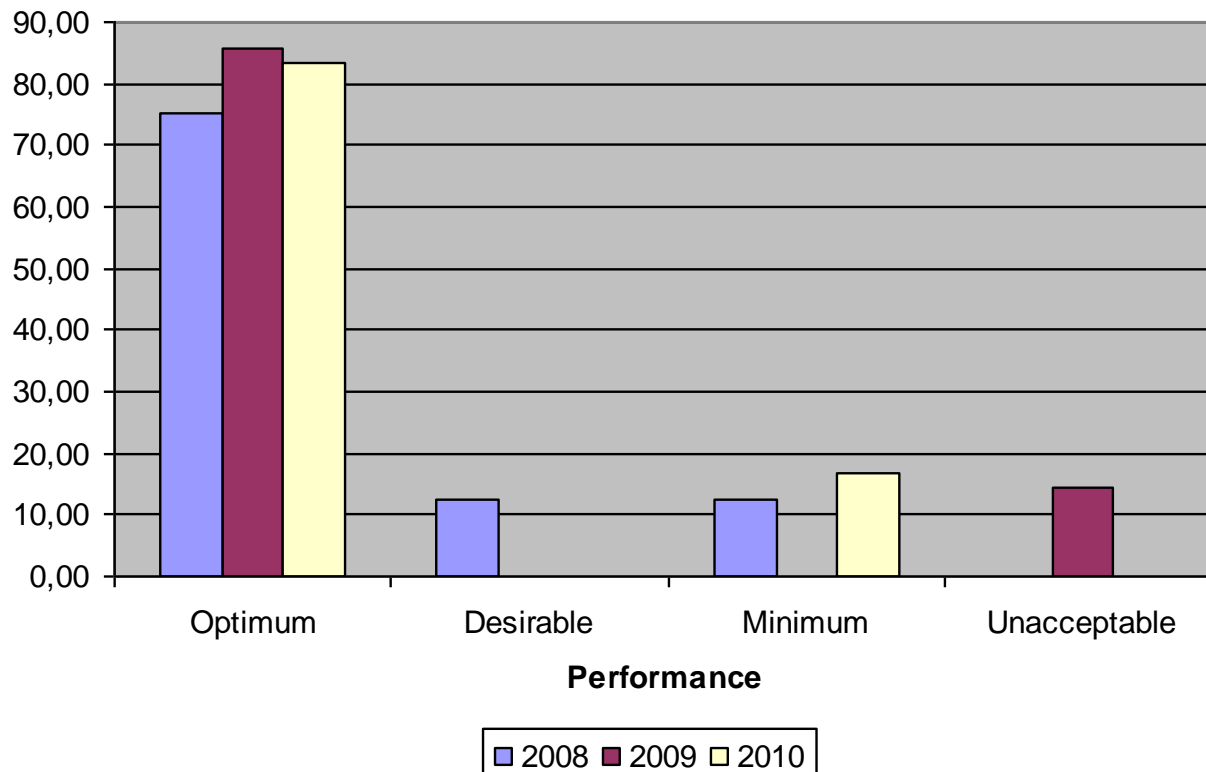
QI-11a



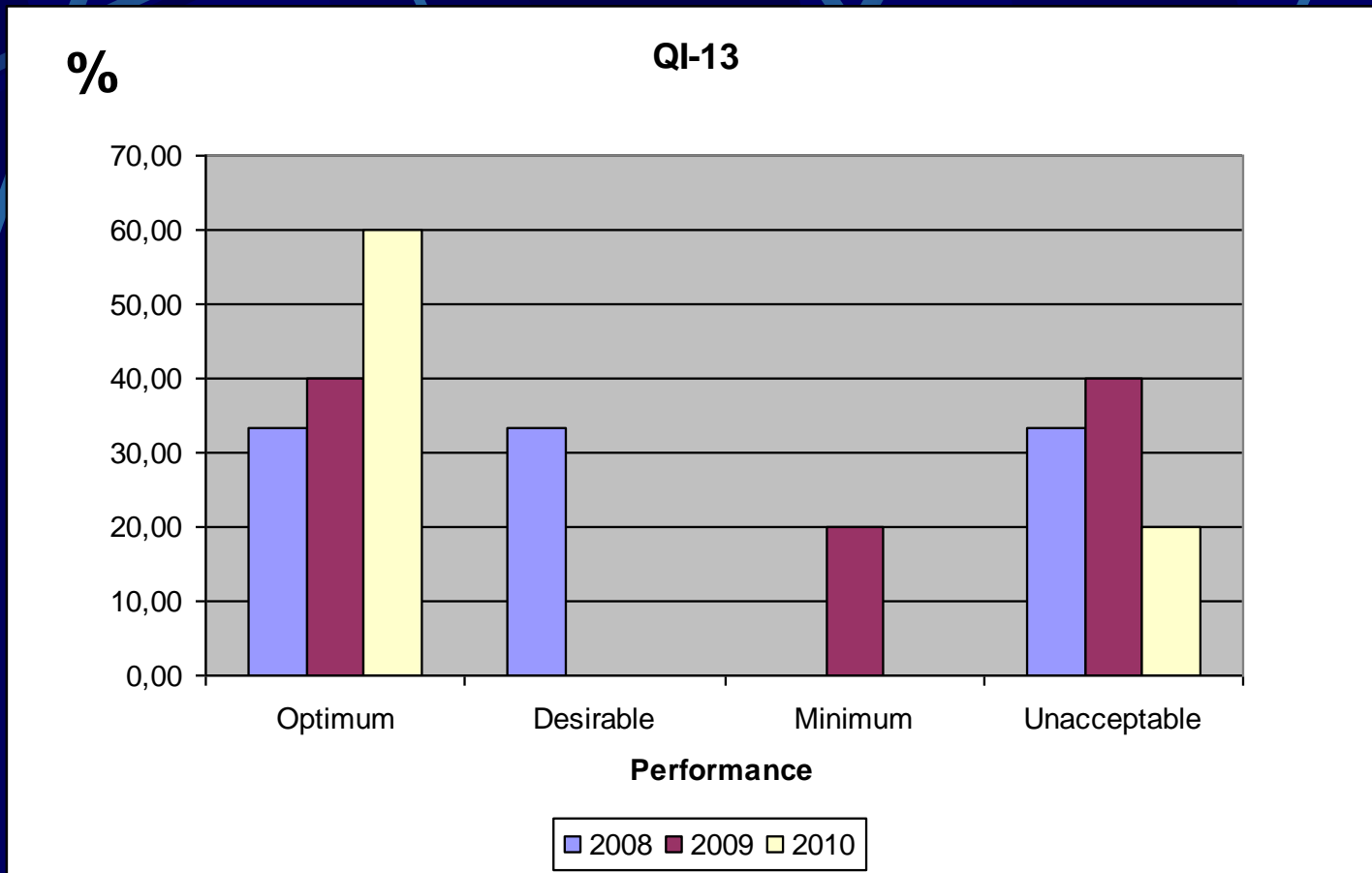
Percentage (Number of samples with insufficient sample volume/ Total number of samples)

%

QI-12



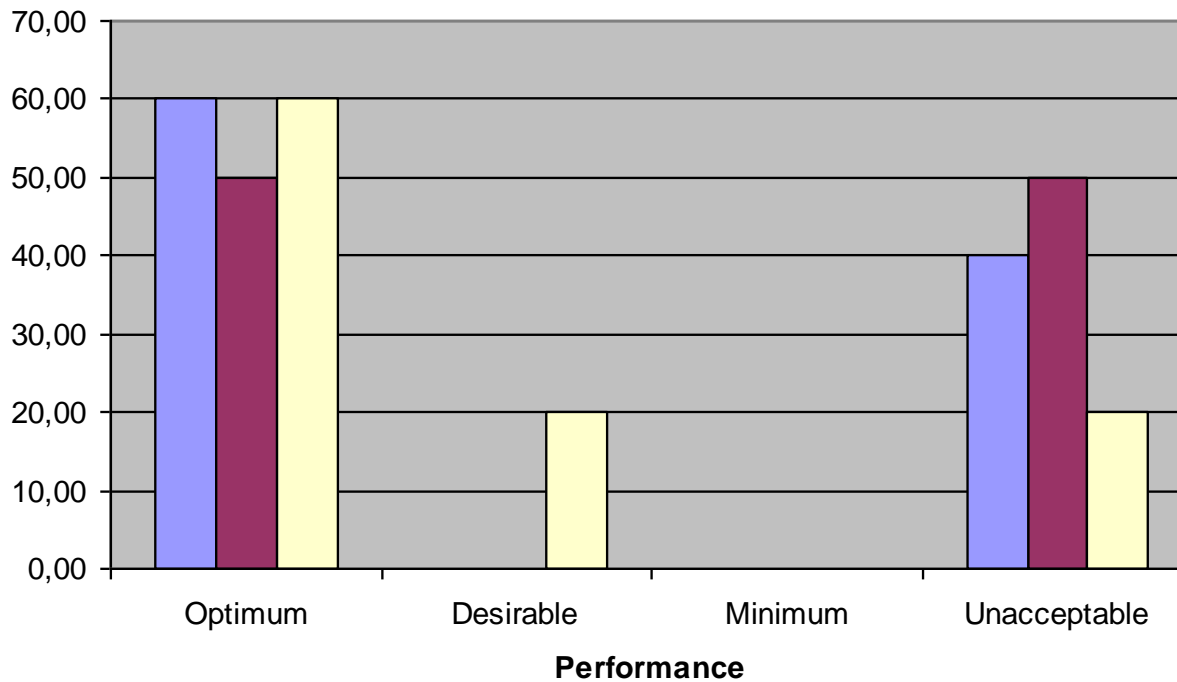
Percentage (Number of samples with inadequate sample-anticoagulant volume ratio/Total number of samples)



Percentage (Number of samples improperly labelled / Total number of samples)

%

QI-15



2008 2009 2010

Tomorrow



Programmi di
Valutazione Esterna di Qualità
Ciclo 2012

Quality Indicators Program



EQA/PT contribution to Pre-Analytical Errors Reduction

Pre-Analytical Issues	Potential Usefulness of EQA/PT
• APPROPRIATENESS IN TEST REQUEST	YES
• PATIENT/SAMPLE IDENTIFICATION	YES
• BLOOD COLLECTION	YES
• SPECIMEN SUITABILITY	YES