

Spirometry Quality Control Grading and Escalation Criteria

Introduction

Spirometry accreditation follows a different path from other Diagnostic Accreditation Program (DAP) accreditation programs. In all other cases, the accreditation award is granted by the DAP Committee based on review of the report generated from an on-site assessment. In pulmonary function level 3 (PF3) hospitals where spirometry is performed, spirometry is assessed as part of the PF3 **on-site** assessment for accreditation.

By contrast, pulmonary function level 2 (PF2) facilities conducting only spirometry testing are not assessed on their premises, but rather assessed using a quality control (QC) program (also referred to as a desktop audit). Successful QC performance will lead to the issuing of an accreditation award every four years for these testing sites. Where unsuccessful QC performance is observed, it will be escalated to the DAP Committee for decision.

This introduction is intended to define the conditions under which a PF2 facilities' QC performance will be escalated to the DAP Committee for action.

Spirometry performance review: QC report grading and escalation

Spirometry results are reviewed by the pulmonary function consultants each cycle. There are two cycles per year—January to June and July to December.

From the data submitted by each facility, three components are reviewed:

- medical interpretation of patient results by the physician
- technical performance of the spirometry test
- quality control, including biologic normal results, and verification of spirometry system linearity with a calibration syringe

The following tables describe how spirometry QC is graded by pulmonary function experts. When unsuccessful QC performance is escalated, the DAP Committee would then determine follow-up actions for the facility in order to maintain their accreditation award.

Performance criteria for the medical interpretation and technical components were developed in conjunction with the Pulmonary Function Advisory Group and the pulmonary function consultants.

Note: Failure to submit spirometry QC data will result in automatic escalation to the DAP Committee for decision regarding status of accreditation award.

Table A - Medical interpretation grade

DAP grade	Definition	Potential risks	Escalation criteria	Escalation action
A	Complete agreement with interpretation	None	N/A	N/A
B	Slight variation, unlikely to affect patient care	None	N/A	N/A
C	Interpretation varies, slight effect on patient care	Reporting a lesser or greater degree of abnormality than is warranted by the data	N/A	N/A
D	Significant variation with immediate effect on patient care	<p>Reporting a patient as normal who is abnormal and vice versa</p> <p>Interpretation as obstructive when restrictive and vice versa</p> <p>Use of inappropriate parameters or criteria to form a diagnosis</p> <p>This could potentially lead to incorrect treatment or unnecessary follow-up</p>	<p>Two in one survey cycle</p> <p>or</p> <p>one in each of two consecutive survey cycles</p>	<p>Request next five patients and resubmit to pulmonary function consultants</p> <p>If data is still unacceptable, forward to consulting respirologist for risk assessment and next steps</p> <p>Prepare a briefing note with the outcome to the DAP Committee¹</p>

Table B - Technical interpretation grade

DAP grade	Definition	Potential risks	Escalation criteria	Escalation action
A	≥80% of test sessions (patient reports) are acceptable	None	N/A	N/A
B	≥70% to <80% of test sessions (patient reports) are acceptable	None	N/A	N/A
C	≥50% to <70% of test sessions (patient reports) are acceptable	Inconsistent results with potential impact on patient results	Two consecutive survey cycles	<ol style="list-style-type: none"> 1. Request next five patients and resubmit to pulmonary function consultants 2. If data is still unacceptable, forward to consulting respirologist for risk assessment and next steps <p>Prepare a briefing note with the outcome to the DAP Committee¹</p>
D	<50% of test sessions (patient reports) are acceptable	Severe inconsistency with strong potential for impact on patient results	One survey cycle	

See next page for definition of acceptable and unacceptable test performance criteria.

¹ If reports correlate and problem has resolved, the DAP Committee briefing note is for information only. If quality assurance concern persists, the briefing note is submitted to the DAP Committee for decision regarding status of accreditation award.

Test performance (technical criteria)	
Acceptable	None of the criteria listed below are observed
Unacceptable	<p>Any or all of the following criteria are observed:</p> <p>Unacceptable calibration</p> <ul style="list-style-type: none"> • Calibration not performed over three flow rates • Expiratory calibration exceeds $\pm 3.0\%$ • Inspiratory calibration exceeds $\pm 5.0\%$ <p>Unacceptable maneuvers</p> <ul style="list-style-type: none"> • Cough or artifact in the first second • Back extrapolated volume (BEV) exceeds 5% of the FVC or 0.100L, whichever is greater • End Forced Expiration (EOFE) not met - less than 25mL change over 1 second or maximum of 15 seconds • Volume of the maximal inspiration (FIVC) following EOFE is greater than FVC, then maneuvers with FIVC - FVC greater than 0.100L or 5% of FVC, whichever is greater are unacceptable • For children age less than or equal to 6 years of age, the difference between the two largest FEV1 values and the two largest FVC values exceed 0.100L or 10% of the highest value, whichever is greater • Poor effort <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>Post-bronchodilator administration</p> <ul style="list-style-type: none"> • Bronchodilator type not indicated on report • Wait time between the last pre-bronchodilator maneuver and the first post-bronchodilator maneuver not included on report • Inadequate wait time for post-testing <p>Unacceptable test session</p> <ul style="list-style-type: none"> • Poor FVC repeatability • Poor FEV1 repeatability • Only one or two acceptable maneuvers • No acceptable maneuvers </div> </div>

Table C - Calibration performance grading

DAP grade	Definition	Potential risks	Escalation criteria	Escalation action
Acceptable	All months demonstrate acceptable calibrations	None	N/A	No
Unacceptable	Any of six months demonstrate unacceptable calibrations Calibration not performed over three flow rates Expiratory calibration exceeds $\pm 2.5\%$ Inspiratory calibration exceeds $\pm 5.0\%$	Patient results are compromised due to excessively large correction factors	One survey cycle	<ol style="list-style-type: none"> 1. Request the facility submit five replicates of this test within one month accompanied by a written action plan 2. If data is still unacceptable, forward to consulting respirologist for risk assessment and next steps 3. Prepare a briefing note with the outcome to the DAP Committee²

² If reports correlate and problem has resolved, the DAP Committee briefing note is for information only. If quality assurance concern persists, the briefing note is submitted to the DAP Committee for decision regarding status of accreditation award.

Table D - Biological QC performance grading

DAP grade	Definition	Potential risks	Escalation criteria	Escalation action
A	Six of six months demonstrate $\leq 3\%$ CV for FVC and FEV1 along with acceptable calibrations	None	N/A	No
B	Any of six months demonstrate $>3\%$ and $<5\%$ CV for FVC and/or FEV1		N/A	No
C1	Three or fewer months reported, all demonstrate FVC and FEV1 $\leq 3\%$ CV ¹	Compromised oversight of facility with potential impact on patient results	One survey cycle ³	No
C2	Any of six months demonstrate ≥ 5 and $<10\%$ CV for FVC and/or FEV1	Inconsistent results with potential impact on patient results	One survey cycle	1. Request the facility submit five replicates of this test within one month

³ Not applicable to new facilities joining partway through a survey cycle.

DAP grade	Definition	Potential risks	Escalation criteria	Escalation action
D1	Any of six months demonstrate $\geq 10\%$ CV for FVC and/or FEV1	Severe inconsistency with strong potential for impact on patient results	One survey cycle	accompanied by a written action plan 2. If data is still unacceptable, forward to consulting respirologist for risk assessment and next steps 3. Prepare a briefing note with the outcome to the DAP Committee ⁴
D2	Three or fewer months reported for second consecutive cycle	Compromised oversight of facility with potential impact on patient results	Two consecutive survey cycles	Prepare a briefing note to the DAP Committee for decision regarding status of accreditation award

Table D - Linearity performance grading - target range of less than or equal to 90mL

DAP grade	Definition	Potential risks	Escalation criteria	Escalation action
A	Six of six months demonstrate all data within target range	None	N/A	No

⁴ If reports correlate and problem has resolved, the DAP Committee briefing note is for information only. If quality assurance concern persists, the briefing note is submitted to the DAP Committee for decision regarding status of accreditation award.

DAP grade	Definition	Potential risks	Escalation criteria	Escalation action
B	One of six months demonstrate data outside target range	None	N/A	No
C1	Two or three of six months demonstrate data outside target range	Inconsistent results with potential impact on patient results	One survey cycle ⁵	No
C2	Three or fewer months reported, all demonstrate data within target range ¹	Compromised oversight of facility with potential impact on patient results	One survey cycle	<ol style="list-style-type: none"> 1. Request the facility submit five replicates of this test within one month accompanied by a written action plan 2. If data is still unacceptable, forward to consulting respirologist for risk assessment and next steps 3. Prepare a briefing note with the outcome to the DAP Committee⁶
C3	Three or fewer months reported, any demonstrate data outside target range ¹	Compromised oversight of facility and inconsistent results with potential impact on patient results	One survey cycle	

⁵ Not applicable to new facilities joining partway through a survey cycle.

⁶ If reports correlate and problem has resolved, the DAP Committee briefing note is for information only. If quality assurance concern persists, the briefing note is submitted to the DAP Committee for decision regarding status of accreditation award.

DAP grade	Definition	Potential risks	Escalation criteria	Escalation action
C4	Calibration syringe validation past due (expired)	Failure to comply with revalidation may result in incorrectly measured volumes and potentially incorrect diagnosis	One survey cycle	Request the facility submit evidence of syringe validation prior to next QC cycle
D1	Four or more of six months demonstrate data outside target range	Severe inconsistency with strong potential for impact on patient results	One survey cycle	<ol style="list-style-type: none"> 1. Request the facility submit five replicates of this test within one month accompanied by a written action plan 2. If data is still unacceptable, forward to consulting respirologist for risk assessment and next steps 3. Prepare a briefing note with the outcome to the DAP Committee⁷
D2	Two or three of six months demonstrate data outside target range for second consecutive cycle	Inconsistent results with potential impact on patient results	Two consecutive survey cycles	
D3	Three or fewer months reported, any demonstrate data outside target range for second consecutive cycle	Compromised oversight of facility and inconsistent results with potential impact on patient results	Two consecutive survey cycles	
D4	Calibration syringe validation past due (expired) for second consecutive cycle	Failure to comply with revalidation may result in incorrectly measured volumes and potentially incorrect diagnosis	Two consecutive survey cycles	Prepare a briefing note to the DAP Committee for decision regarding status of accreditation award

⁷ If reports correlate and problem has resolved, the DAP Committee briefing note is for information only. If quality assurance concern persists, the briefing note is submitted to the DAP Committee for decision regarding status of accreditation award.