Diagnostic Accreditation Program

MANUAL

Spirometry Quality Control Plan

2. Print out a copy of the calibration results. The measured values must be between 2.910 and 3.090 liters.
3. Verify

Spirometer calibration

Calibration syringe requirements

To achieve accurate and reproducible spirometry results, measurements from your spirometer should be regularly checked against a precision calibration syringe. The "Standardization of Spirometry 2019 Update"[1] requires daily calibration or calibration checks of flow and volume spirometers using a validated 3-L calibration syringe with an accuracy of ± 15 mL or ± 0.5%.

Calibration is the procedure for establishing the relationship between sensor-determined values of flow or volume, and the actual flow or volume, using a validated 3-L calibration syringe. Calibration should be performed daily or prior to use. Follow manufacturer's instructions. Spirometer should be set to calibration mode.

A calibration check is different from calibration and is the procedure used to validate that the spirometer is within calibration limits, that is to say ± 3.0% of true. A calibration check is required daily or prior to patient testing. Spirometer should be set to calibration check mode. There are no spirometers on the market currently that may be used without at least a calibration check.

Syringe revalidation: As wear and tear can affect the accuracy of the 3-L calibration syringe over time, it should be re-validated as determined by the expiry date on the certificate of calibration, or every two years if the expiry is undefined. There are a number of companies that perform revalidation services of calibration syringes. Proof of syringe validation must be submitted annually to the DAP.

Syringe leak test: The 3-L calibration syringe should be tested for leaks and smoothness of operation minimally on a weekly basis. The syringe should be tested from a full (drawn back) position by placing a hand over the outlet and depressing the syringe handle gently. No air should escape. Secondly the syringe should be emptied, and in an empty position should be checked by again placing a hand over the outlet, then pulling gently on the syringe handle. No air should enter the syringe. Syringes that leak may not measure proper volume and should be sent for service and revalidation.

Syringe smoothness test: Move the syringe handle back and forth to check that the action is smooth, without catching or stuttering. Syringes that do not move smoothly may not deliver proper volume and should be sent

Enter ambient conditions

The facility must have a room thermometer with an accuracy of ± 10°C. If barometer and/or hygrometer are not available, barometric pressure and relative humidity may be recorded from local weather station sources. From your thermometer, barometer and hygrometer enter:

1. Temperature

2(1.)]TJETQq0.00000912 0 612 792 reW*nBT/F4 11 Tf1 0 0 1 99.02517.0 6i8q0.00000912 0 61reW*q141 11

Perform calibration or calibration check

1. Set spirometer to calibration mode or calibration check mode.
2. If filters designed specifically for spirometry testing are used, calibration or calibration checks should be done through the filter.
3. Perform a calibration or calibration check using the validated 3-L calibration syringe according to the ATS/ERS statement “Standardization of Spirometry 2019 Update.”[1] Pull the syringe handle out completely and push the 3-L volume into the spirometer at the correct flow.
4. Repeat the calibration or calibration check at least three separate times at three different flow rates, as per manufacturer instructions.
5. Ensure the calibration results are within the required limits ± 3.0% (or 2.91 liters to 3.09 liters).
6. Maintain a copy of the calibration or calibration check in the logbook.
7. Submit a copy of the calibration or calibration check to the DAP for each day of BioQC and patient results submitted in the semi-annual QC package.

c. Perform a minimum of three linearity tests (flow volume loops):

   i. one maneuver will be performed with a peak flow of less than two liters/sec

   ii.

reporting at BTPS automatically employ correction factors, at specific temperatures, that convert ATPS to BTPS. Here is an example for an ambient temperature of 21°C:

Volume of 3-L syringe = 3.00 L

Correction factor at 21°C = 1.096

Therefore: 3.00 L x 1.096 = 3.288 L

Acceptable accuracy is ± 3.0%. Therefore:

- L minus 3.0% = 3.189 L
- plus 3.0% = 3.387 L

The acceptable range at 21°C is 3.189 L–3.387 L

The chart below has already calculated the acceptable ranges at each temperature for spirometers reporting at BTPS. In order to verify the accuracy of your measurement, use the chart to determine the FVC acceptable range for each trial, at your ambient temperature:

BTPS Chart for Acceptable Ranges (± 3.0%)

Factor	oC	Acceptable range (L)	Factor	oC	Acceptable range (L)	Factor	oC	Acceptable range (L)
1.118	18	3.253–3.455	1.085	23	3.157 - 3.353	1.057	28	3.076–3.266
1.111	19	3.233–3.433	1.080	24	3.143 - 3.337	1.051	29	3.058–3.248
1.102	20	3.207–3.405	1.075	25	3.128 - 3.322	1.045	30	

Linearity test flow volume loops	Trial 1: Low flow (less than 2 L/sec)	Trial 2: Mid flow (4 to 6 L/sec)	Trial 3: High flow (greater than 8 L/sec)	Difference in FVC (highest minus lowest: should be < or = 90 mL)
FVC (liters)	3.24	3.18	3.26	0.080 L (80 mL)
Peak expiratory flow				

Biological control (BioQC) testing

A biological normal quality control (BioQC) refers to a healthy non-smoking individual with normal and stable lung function, who is tested on a regular basis as a “control.” Frequently office personnel are asked to perform this function. BioQC should