



## DIAGNOSTIC ACCREDITATION PROGRAM

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# DAP SPIROMETRY QUALITY CONTROL PLAN



## *DAP SPIROMETRY QUALITY CONTROL PLAN*

Spirometry is a useful diagnostic test commonly performed in a variety of settings; however accurate results are dependent on careful technique, and proper equipment calibration and maintenance. The American Thoracic Society (ATS) and European Respiratory Society (ERS) have recommended a number of procedures to reduce variability including the weekly testing of flow volume measurements. Under the College of Physicians & Surgeons of British Columbia, Diagnostic Accreditation Program (DAP) Spirometry Quality Control Program, facility personnel at each site will perform quality control procedures according to the DAP protocol. Only one set of data is required from each spirometer. If the spirometer is used in more than one site, the patient data submitted should be representative of this.

Results are submitted to the DAP twice a year and will give an indication if any areas of concern exist with the spirometer or performance of the tests. An individual report with recommendations will be sent to the facility at the end of each reporting cycle.

Level 1 and Level 2 (formerly known as Category IIA and IIB) facilities and private clinics performing spirometry require participation in the DAP Spirometry Quality Control Program as part of their accreditation. Continuing accreditation is based upon the satisfactory review of quality assurance and control data submitted to the DAP.

Exemption: If the spirometer used exclusively is the **COPD-6** spirometer, as approved by the Medical Services Commission for case finding, DAP accreditation is not required.

The DAP Spirometry QC Program follows the recommendations of the American Thoracic Society and European Respiratory Society Task Force: *“Standardisation of Lung Function Testing: Standardisation of spirometry”* (2005)<sup>1</sup>.

## SPIROMETRY DEFINITIONS AND REQUIREMENTS

**Calibration/ Calibration Check:** “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. Current ambient conditions are entered prior to calibration and the injection rates are varied according to equipment manufacturer’s recommendations to *adjust* the output with a known input volume. “Calibration Check” is different in that it does not adjust the spirometer; rather it verifies that the spirometer is within calibration limits. As the validated QC syringe may lose accuracy over time, re-validation is performed according to manufacturer’s recommendations. Proof of re-validation is submitted to the DAP annually.

**Linearity Testing:** A spirometer is considered linear if its output is directly proportional to its input, regardless of the flow rate. Loss of linearity is a primary problem with flow sensing spirometers, therefore syringe flow volume loops are performed on a weekly basis to ensure system linearity. The therapist injects the full volume of the validated 3-L syringe into the spirometer at various rates and records the reported volumes. The peak flow rates include one injection at a rate of less than 2 liters per second, one injection at a rate of 4 to 6 liters per second, and one injection at a rate of greater than 8 liters per second. The FVC results must be within the acceptable ranges and the maximum difference between the reported volumes should be less than .105 liters (105 mL) to document that the equipment is within control limits. Enter one set of linearity data per month on the DAP worksheets provided, and include the graphical printout. Data is submitted twice per year, on or before January 15<sup>th</sup> and July 15<sup>th</sup>.

**Biologic Controls (BioQC):** A healthy non-smoking individual will perform spirometry testing monthly to assess the overall operational status of the spirometry system. Results are monitored to assess changes in equipment performance that may be undetected in routine calibration. A second BioQC subject should be identified and able to fill in if the primary BioQC subject cannot perform this function due to absence or illness. Enter one set of BioQC data per month on the DAP worksheets provided. Data is submitted twice per year, on or before January 15<sup>th</sup> and July 15<sup>th</sup>.

### *Spirometry Requirements:*

- The spirometer must be able to accumulate volume for greater than 15 seconds and measure a volume of greater than 8 liters (BTPS) with an accuracy of  $\pm 3\%$  of reading or  $\pm 0.05$  liters, whichever is greater.
- The facility must have a room thermometer with an accuracy of  $\pm 1^{\circ}\text{C}$ .
- If room temperature changes by more than  $2^{\circ}\text{C}$ , then another calibration must be performed prior to patient testing.
- Measure height of patients and BioQC subjects accurately.
- Calibration or calibration checks are performed daily or prior to patient testing.
- Linearity checks (flow volume loops) should be performed weekly and after equipment repairs, maintenance or software changes.
- A biologic control (BioQC) should be performed monthly and after equipment repairs, maintenance or software changes.
- A log of all relevant testing data, service, repairs or software changes, should be maintained.

## SPIROMETRY QUALITY CONTROL PLAN

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The term “quality control” can be defined as the process of monitoring the accuracy and reproducibility of a test procedure but it also takes into account a number of aspects, any one of which may impact patient results. These include the components that make up the pre-test, test, and post-test:

- Patient education and preparation
- Procedure
- Equipment
- Reporting of results

The following chart outlines the steps necessary to ensure proper functioning of the spirometry equipment, and the frequency with which they need to be performed by the therapist, in order to produce accurate patient results. Detailed instructions follow in each section.

Equipment	Procedure	Frequency	ATS/ERS Limits of Acceptability / Recommended Limits
Spirometer	Calibration or Calibration Check with 3-L calibration syringe	Daily or prior to patient testing	$\pm 3.5\%$ of 3 L (2.895 – 3.105 L)
Spirometer	Linearity tests with 3-L calibration syringe	Weekly	Loops at these flow ranges: < 2 L/s, 4 L/s to 6 L/s, > 8 L/s  *see p.14-15 for acceptable results
Spirometer	Biologic control (BioQC)	Monthly	FVC and FEV1 < 3% PEFR < 10%
Syringe	Leak test	Weekly	No leaks

*Daily Quality Control: (see p.9 to 11)*

1. Perform Calibration or Calibration Check at least daily or prior to patient testing, as per manufacturer recommendations.
2. Print out a copy of the calibration results. The measured values must be between 2.895 – 3.105 liters.
3. **Verify that the calibration has passed (see #2 above) prior to patient testing.**

*Weekly Quality Control: (see p.12 to 17)*

1. Perform 3-L calibration syringe leak test.
2. Perform linearity test with a validated 3-L calibration syringe run in a patient file, named “Syringe, QC”, and record results on the DAP Monthly Spirometry Linearity Testing worksheets.
3. **Verify that the linearity tests fall within the acceptable ranges for accuracy and reproducibility.**

*Monthly Quality Control: (see p.18 to 19)*

1. Perform BioQC testing: The biologic normal control is performed in the patient file designated for that individual (e.g. BioQC1 or BioQC2). Only one (1) BioQC is required to be tested each month. When this data is entered into the DAP Spirometry QC worksheets, a number of calculations are performed automatically. Unexpected changes in the BioQC values may alert the user to equipment problems that were not present, or undetected, when calibration procedures were performed.
2. **Verify that the BioQC values are acceptable based on their established ranges.**

### *Semi-annual Reporting:*

3. Submit to the DAP on or before January 15<sup>th</sup> and July 15<sup>th</sup>:
  - a. Worksheets for linearity report (including print-out of graphical data).
  - b. Worksheets for BioQC results (including print-outs of graphical data).
  - c. Calibration print-outs for day of each monthly BioQC result submitted.
  - d. Print-outs of 10 random and anonymized patient spiromgrams with interpretation, performed during the 6 month reporting period.

### *Log Book:*

A log book should be kept to record the following:

- Ambient temperature
- Barometric pressure
- Relative humidity
- Calibration FVC values with the 3-L syringe
- Calibration pass or fail
- Leak test pass or fail
- Equipment service, troubleshooting performed, software upgrades, etc.

Example of Log Book:

Date	Initials	Temp °C	BP mm/Hg	RH%	Calibration: FVC (2.895 – 3.105 )	Cal P/F	Leak test	Comments
24/08/12	SW	21	756	72	3.02	Pass	Pass	ATS 2005 software upgrade



## *SPIROMETER CALIBRATION*

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### *Calibration Syringe Requirements:*

In order to achieve accurate and reproducible spirometry results, measurements from your spirometer should be regularly checked against a precision calibration syringe. The 2005 ATS/ERS statement “Standardisation of Spirometry”<sup>1</sup> requires daily calibration or calibration checks of flow and volume spirometers using a validated 3 liter calibration syringe with an accuracy of  $\pm 15$  mL or  $\pm 0.5\%$ .

*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  $\pm 3.5\%$  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 re-validation:* As wear and tear can affect the accuracy of the 3-L calibration syringe over time, it should be re-validated on a yearly basis or as specified by the manufacturer. There are a number of companies that perform re-validation 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.

*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 for service.

### *Performing Calibration or a Calibration Check:*

Calibration or calibration checks must be performed every day prior to patient testing or when quality control is performed. Check your manufacturer's manual for calibration or calibration check directions. The directions will be labeled as a "Calibration" or a "Calibration Check". Some systems are calibrated at the manufacturer's site but still require a calibration check daily or prior to patient or quality control testing.

The following instructions may not be specific to your spirometer, but the examples are meant to represent how the data may look. The displays will vary slightly based on the spirometer you are using.

### *Enter Ambient Conditions:*

The facility must have a room thermometer with an accuracy of  $\pm 1^{\circ}\text{C}$ . 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:

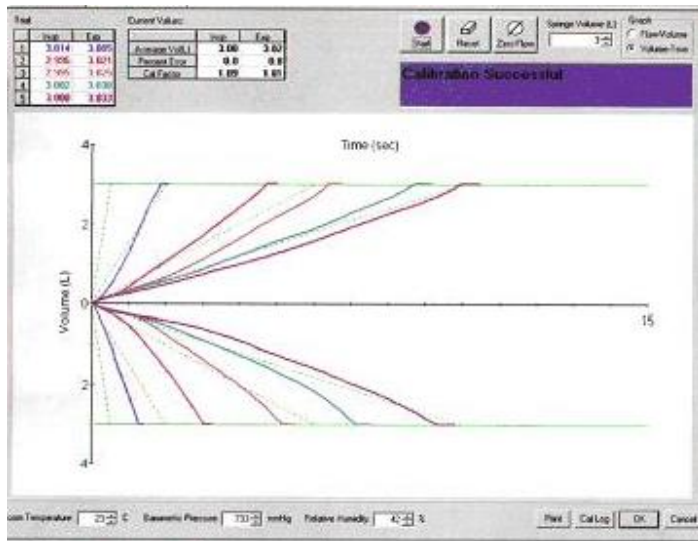
1. Temperature
2. Barometric pressure
3. Humidity



### *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 2005 ATS/ERS statement "Standardisation of spirometry"<sup>1</sup>. Pull the syringe handle out completely and push the 3 liter 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  $\pm 3.5\%$  (or 2.895 liters to 3.105 liters).
6. Maintain a copy of the calibration or calibration check in the log book.



## *SPIROMETER LINEARITY TESTING*

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A spirometer is considered linear if its output is directly proportional to its input regardless of flow rate. The resulting volumes should be accurate and reproducible. The 2005 ATS/ERS statement “Standardisation of Spirometry”<sup>1</sup> states that linearity testing must be performed weekly. The DAP Spirometry QC Program requires that only one of those tests be recorded for each month on the *Monthly Spirometry Linearity Testing* worksheet.

The linearity test is completed by performing “syringe flow volume loops” to simulate patient testing with a known volume at varying flows. Set the spirometer to “Patient” mode and inject air from a 3-L syringe at a slow, moderate, and fast flow rates. The FVC volumes achieved at each of these flow rates should meet both the accuracy requirement of  $\pm 3.5\%$ , and should show reproducibility to within 105 mL from highest to lowest flow rate (see sections A and B on pages 14 and 15).

### *Linearity Testing:*

1. Enter ambient conditions as described on page 10
2. Perform a calibration or calibration check using the 3-L syringe, as described on page 11.
3. Set up a mock patient study. Enter the patient data as follows:
  - First Name: QC
  - Last Name: *Syringe*
  - Weight: 150 lbs. (or 68 kg)
  - Height: 64 in. (or 163 cm)
  - Age: 40

The screenshot shows a software window titled "Patient Details" with a blue header bar. Below the header are four tabs: "Patient Info.", "Respiratory History", "Resp. Hist. (cont.)", and "Notes". The "Patient Info." tab is active. The form contains the following fields and values:

- ID #: 123456 (Red fields required)
- First Name: QC (Red fields required)
- Last Name: Syringe (Red fields required)
- Street: (empty)
- City: (empty)
- State/Prov: (empty)
- Zip: (empty)
- Birthdate: 12/24/1951
- Location ID: (empty)
- Ethnic Origin: Caucasian (dropdown menu)
- Height: 64.0
- Weight: 150
- Gender: Male (radio button), Female (radio button, selected)

4. Perform Linearity tests (flow volume loops) as shown below. The results should pass the **accuracy** and **reproducibility** verification as described on page 14 and 15:
  - a. Set spirometer to “Patient” mode. Attach a 3-L syringe to the spirometer with a tight seal with no leaks.
  - b. Withdraw syringe until fully inflated to a full 3 liters.
  - c. Inject air into the spirometer at low, mid and high separate speeds (see below):
    - One maneuver will be performed with a peak flow of less than 2 liters/sec
    - One maneuver will be performed with a peak flow between 4 and 6 liters/sec
    - One maneuver will be performed with a peak flow greater than 8 liters/sec
  - d. Perform a minimum of 3 linearity tests (flow volume loops)

A. Acceptable results at ambient temperature (accuracy verification):

Spirometers may measure volume at body temperature (BTPS) or at ambient/room temperature (ATPS). Most spirometers in physicians’ offices will report at BTPS.

Spirometers 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:  $3.00 \text{ L} \times 1.096 = 3.28 \text{ L}$
- Acceptable accuracy is  $\pm 3.5\%$ . Therefore:
  - $3.28 \text{ L} \text{ minus } 3.5\% = 3.17 \text{ L}$
  - $3.28 \text{ plus } 3.5\% = 3.40 \text{ L}$
- The acceptable range at 21°C is: 3.17 L – 3.40 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 ( $\pm 3.5\%$ )								
Factor	$^{\circ}\text{C}$	Acceptable Range (L)	Factor	$^{\circ}\text{C}$	Acceptable Range (L)	Factor	$^{\circ}\text{C}$	Acceptable Range (L)
1.118	18	3.24 – 3.47	1.085	23	3.14 – 3.37	1.057	28	3.06 - 3.28
1.111	19	3.21 – 3.45	1.080	24	3.13 – 3.35	1.051	29	3.04 - 3.26
1.102	20	3.19 - 3.42	1.075	25	3.11 – 3.34	1.045	30	3.03 - 3.25
1.096	21	3.17 – 3.40	1.068	26	3.09 – 3.32			
1.091	22	3.16 – 3.39	1.063	27	3.08 - 3.30			

B. Acceptable difference in FVC at 3 flow rates (reproducibility verification):

In order to determine if your spirometer meets reproducibility requirements across various flow rates, the volumes should fall within 105 mL from largest FVC to smallest FVC. Examples below:

Example 1: Difference in FVC from highest to lowest result: *Acceptable*

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 $< \text{or} = 105 \text{ mL}$ )
FVC (liters)	3.24	3.18	3.27	.090 L (90 mL)
Peak Expiratory Flow (liters/sec)	1.56	5.46	10.02	

**NOTE:** The largest FVC trial (3.27) minus the smallest FVC trial (3.18) is less than .105 L (105 mL) and is therefore acceptable. The peak flows are also within the required ranges (less than 2 L/s, 4-6 L/s and greater than 8 L/s).

Example 2: Difference in FVC from highest to lowest result: *Not acceptable*

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 = 105 mL)
FVC (liters)	3.08	3.28	3.16	.20 L (200 mL)
Peak Expiratory Flow (liters/sec)	2.56	5.46	10.02	

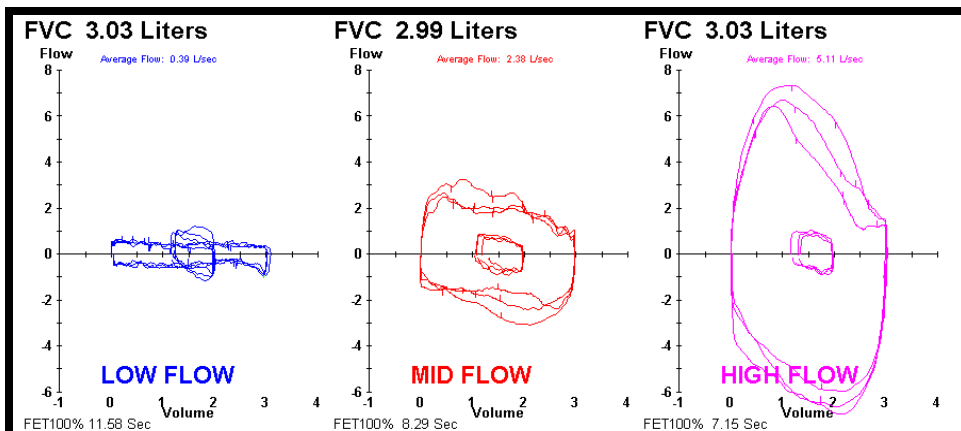
**NOTE:** The largest FVC trial (3.28) minus the smallest FVC trial (3.08) is greater than .105 L (105 mL) and therefore is *not* acceptable. Also, the Peak Expiratory Flow for Trial 1 is 2.56, which is higher than the requirement of less than 2 L/sec and therefore would *not* be considered an acceptable trial.

5. Print out the following:

- All linearity tests displaying each loop at each flow and the actual numeric results.
- Ambient temperature is an integral piece of information that **must** be recorded somewhere on the flow volume loops print-out.

Please see the example below. This illustration is only meant to show that the three flow rates are different. Actual flow rates should be:

- Less than 2 liters / second
- 4 to 6 liters / second
- Greater than 8 liters / second:



6. Submit *Linearity Testing* worksheets: Even though Linearity testing is performed weekly, only one of those tests should be recorded for each month on the *Monthly Spirometry Quality Control Program* worksheet (tab labeled **Linearity**).
  - Go to the DAP website ([www.dap.org](http://www.dap.org)) under *Proficiency > Pulmonary Function > Spirometry QC* and save the *Monthly Spirometry Quality Control Program* worksheets to your computer.
  - Fill in the values generated for FVC and FEV1 and calculate the highest reading minus the lowest FVC on the Monthly Spirometry Linearity Testing worksheet.
  - Confirm that FVC and FEV1 values are within acceptable limits.
  - Attach the corresponding graphical print-out.
  
7. The 6 month data set is submitted to the DAP on or before January 15 and July 15.



## BIOLOGICAL CONTROL (BIOQC) TESTING

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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 be performed monthly and reported on the DAP *Monthly Spirometry Quality Control Program* worksheets.

Each site should identify two (2) individuals with normal lung function who are available to perform BioQC spirometry. However, only one (1) individual is required to perform monthly BioQC spirometry. The second person should be available to fill in if the primary BioQC subject cannot perform this function due to absence or illness.

### *Establishing the BioQC Normal Range:*

1. In order to establish the normal ranges for the primary and backup BioQC subjects, a minimum of 10 replicates are required. Twenty replicates is the recommendation for statistical accuracy, however 10 replicates will give an adequate baseline with which to compare the monthly QC results.
2. Perform 10 to 20 replicates on each BioQC subject over a period of several days. Ideally this should entail a single test performed each day; however a maximum of 2 tests spread out within any single day (e.g. morning and afternoon) may be used.
3. Use the *Normal Range Calculator* to determine the acceptable ranges for each person. This worksheet takes the average of the replicates and calculates two standard deviations (SD) which constitutes the normal range for this subject.
  - Go to the DAP website ([www.dap.org](http://www.dap.org)) under *Proficiency > Pulmonary Function > Spirometry QC* and save the *Normal Range Calculator* to your computer. The *Normal Range Calculator* is also the last tab on the *Monthly Spirometry Quality Control Program* worksheets.
  - Fill in the values generated by the BioQC subjects. The average, standard deviation (SD) and coefficient of variation (CV) will automatically be calculated.
  - There should be a maximum of 10% between the highest and lowest FVC and FEV1 values
  - The calculated coefficient of variation (CV) should be 3% or less.
  - If your site does not have access to Excel, submit the data to the DAP for normal range calculations.

4. Subsequent spirometry testing on each BioQC subject should fall within the  $\pm 2$  SD ranges for that subject. The facility should perform troubleshooting if BioQC values fall outside of their acceptable ranges.

### *Monthly BioQC Testing:*

1. The BioQC subject should perform spirometry procedures in the same way as a patient.
2. For consistency, the BioQC subject should ideally be tested:
  - a. on the same spirometer
  - b. on the same day of month
  - c. at the same time of day
3. An adequate test requires a minimum of three acceptable FVC maneuvers and adherence to repeatability criteria.
  - Repeatability is achieved when the difference between the largest and the next largest acceptable FVC and FEV1, is less than or equal to 150 mL. The results for FVC and FEV1 do not need to come from the same maneuver.
  - The best trial is chosen based on the largest sum of FVC plus FEV1 from acceptable maneuvers.
4. The BioQC result should be recorded for each month on the *Monthly Spirometry Quality Control Program* worksheets.
  - Go to the DAP website ([www.dap.org](http://www.dap.org)) under *Proficiency > Pulmonary Function > Spirometry QC* and save these forms to your computer.
  - Fill in the values generated by the BioQC subject(s). The average, standard deviation (SD) and coefficient of variation (CV) will automatically be calculated.
  - The CVs for FVC and FEV1 should be less than or equal to 3%.
  - Confirm that the results fall within the acceptable ranges for this BioQC subject.
  - If your site does not have access to Excel, submit the data to the DAP for BioQC calculations.
5. Data from different BioQC subjects must be recorded on separate worksheets (see tabs at the bottom of the spreadsheet). Do not mix BioQC #1 data with BioQC #2 data.
6. BioQC results are submitted along with that day's calibration report, to the DAP twice each year on or before January 15<sup>th</sup> and July 15<sup>th</sup>.

## *PREDICTED SETS*

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The National Health and Nutrition Survey (NHANES) III (1999) is the ATS-ERS recommended source of normal values for ages 4 to 80.

## *SUBMISSION OF DATA TO THE DAP*

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**QC must be reviewed and signed off by the physician in charge.**

Completed data may be submitted to DAP PT/QC Specialist by any of the following:

- Scan /email to: [ptqc@cpsbc.ca](mailto:ptqc@cpsbc.ca)
- Fax to 604-733 3503 Attn: DAP PT/QC
- Mail to:
  - Attn: DAP PT/QC
  - Diagnostic Accreditation Program
  - College of Physicians & Surgeons of British Columbia
  - 300 – 669 Howe Street
  - Vancouver BC V6C 0B4

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## **References:**

- 1 Miller MR, Hankinson J, Brusasco V, et al. Standardisation of spirometry. Eur Respir J 2005; 26: 319-338