Print Instructions

NIOSH Spirometry Facility Application Form – Instruction Sheet & Example

NOTE: Click the **Reset Form** box at bottom of the page to **delete** all entries and start over. The following commands are also at the bottom of the form: **Save Form**, **Email Form**, and **Print Form**.

Spirometry Facility Certification Form

Section 1 Facility Facility Name South Clinic Telephone number 000-000-0000 Email Sclinic@nn.net

Street Address 123 Smith Drive City Jamestown State MS Zip Code 10111 County Clairton

Type of Facility (Mobile, Clinic, Private Office, Hospital) Clinic How many spirometry tests per year? 500

Section 1: Fill out the top portion of the form as indicated. Telephone number and email should be listed for the primary contact at the facility.

Section 2 Spirometry System(s) * Items are required	Unit 1	Unit 2
A. Room number (if applicable)	13	
B. Manufacturer *	Spiro-Med	
C. Model *	Flow 2	
D. Serial #	825001	
E. Date acquired	03/01/2010	
F. Spirometer validation letter (attached)*	☒ Yes	☐ Yes
G. Spirometer automated quality control*	☒ Yes	☐ Yes
H. Calibration check available*	☒ Yes	☐ Yes
I. Graphical Displays		
1. Meets 2005 ATS/ERS Standards*	☒ Volume-Time ☐ Flow-Volume	☐ Volume-Time ☐ Flow-Volume
2. Real-time during testing*	☒ Volume-Time ☐ Flow-Volume	☐ Volume-Time ☐ Flow-Volume
J. Test report for interpreter (sample attached)	☒ Yes	☐ Yes
K. Spirometry data file		
1. Stores 2005 ATS/ERS parameters*	☒ Yes	☐ Yes
2. Stores all maneuvers	☒ Yes If NO, max # ____	☐ Yes If NO, max # ____
3. Electronic output format*	☐ 2005 ATS/ERS ☒ NIOSH-approved	☐ 2005 ATS/ERS ☐ NIOSH-approved

Section 2: Complete the following:

A. Room number : If applicable

B. Manufacturer: Name of manufacturer

C. Model: Specific model type and software version for each spirometer to be used during CWHSP spirometry testing

D. Serial #: Serial number of spirometer

E. Date acquired: Date spirometer was acquired. If equipment software has been updated, provide the most recent software version number.

F. Spirometer Validation Letter: Manufacturers should provide an independent laboratory validation letter affirming that each spirometer model used by your facility has passed a 24 standard volume-time waveform testing procedure as outlined in the *ATS 1994 Update for Standardization of Spirometry*. Each spirometer manufacturer should be able to supply you with a copy of this letter.

Section 2 continued: Complete the following:

G. Spirometer Automated Quality Control: Check "Yes" if your spirometer automatically alerts the technician of possible **technical errors** (i.e., cough in the first second, hesitation or excessive extrapolated volume, lack of test repeatability, etc.) **before** the test session is exited.

H. Calibration Check Available: The technician can check the accuracy of the volume measured by the spirometry system as needed. It is preferred that a sample calibration report for each spirometer be submitted.

I. Graphical Displays: Must meet standards for minimum accuracy, precision, and range of measurement as described in Table 2 (below) of the 2005 ATS/ERS Standardisation of Spirometry. Note that the table includes minimum scale for instrument real-time display and printed graphs. Both V/T and F/V curves must be visible in real-time display and printed on test reports. A test report with sample graphs is included later in this document (pages 8-13). Since both graphs will be printed, a graphical output scale factor of 10 mm/sec. is acceptable according to ATS/ERS guidelines.

Table. 2—

Recommended minimum scale factors for time, volume and flow on graphical output

	Instrument display		Hardcopy graphical output	
Parameter	Resolution required	Scale factor	Resolution required	Scale factor
Volume#	0.050 L	5 mm·L^{-1}	0.025 L	10 mm·L^{-1}
Flow#	0.200 L·s^{-1}	2.5 mm·L^{-1}·s^{-1}	0.100 L·s^{-1}	5 mm·L^{-1}·s^{-1}
Time	0.2 s	10 mm·s^{-1}	0.2 s	20 mm·s^{-1}

#: the correct aspect ratio for a flow *versus* volume display is two units of flow per one unit of volume.

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J. Spirometry Test Report for NIOSH: Submit a **hardcopy or pdf (**acceptable until February 2018). Test reports must contain the following:

1. Clinic name, facility approval number, city, state, zip code
2. Miner's name and medical record number
3. Miner's age, sex, race, height, and weight
4. Miner position during testing (standing or sitting)
5. Room temperature, barometric pressure
6. Technician's CWHSP identification number
7. Dates and time of test and last calibration check
8. Numerical values for all attempted trials [FVC, FEV6, FEV1, FET, PEF, (FEV1/FVC, FEV1/FEV6 – calculated from highest values)] and back extrapolated absolute volume is strongly recommended (i.e. volume, not percent). Common abbreviations for back extrapolation are: Vext, BEV, EV.
9. Test repeatability for FVC and FEV1
10. Volume-time and flow-volume graphs for all attempted trials

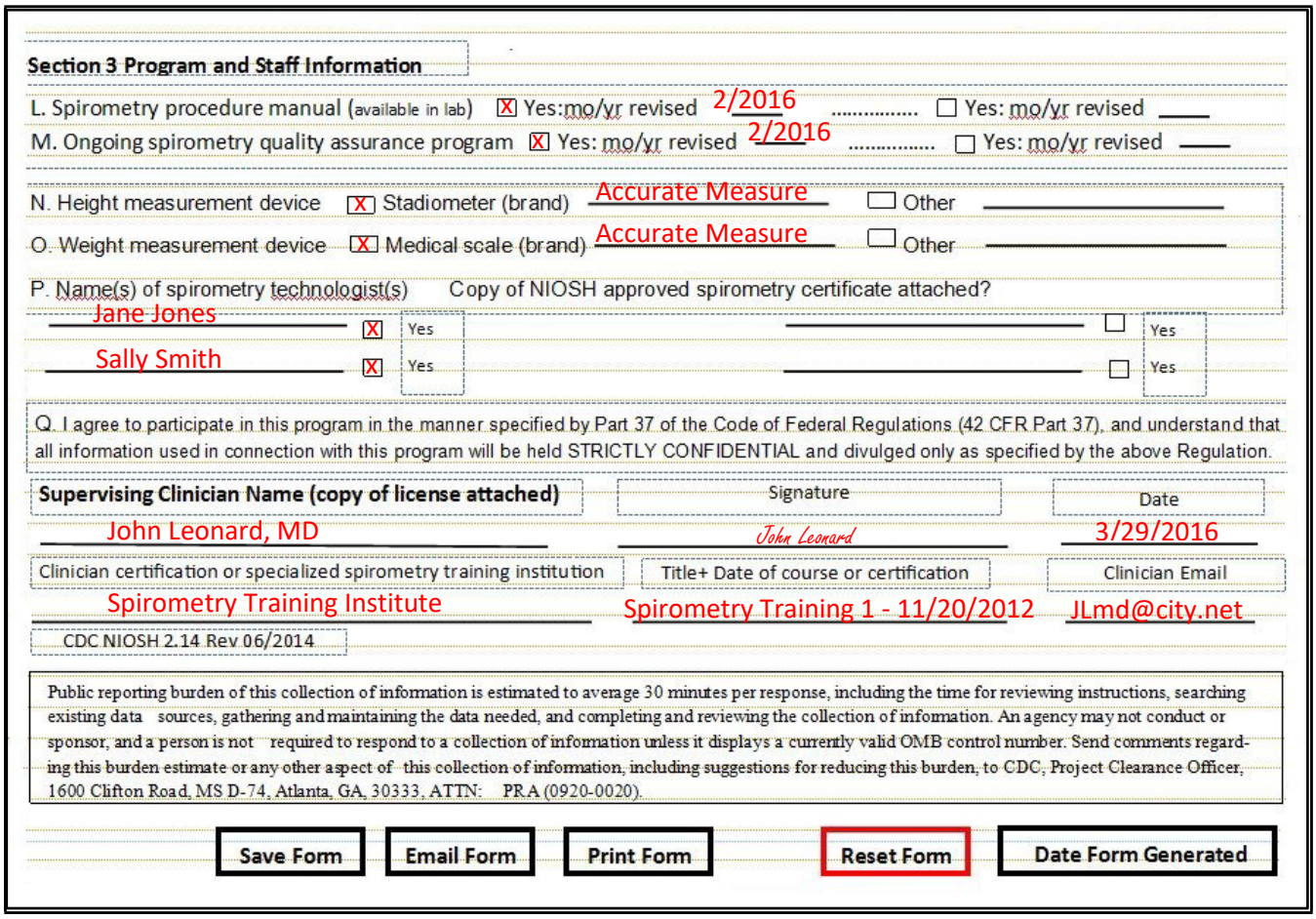
    - **Option 1:** Curves are **staggered** at ATS/ERS size standards (± 1 mm size variation acceptable) for both volume-time and flow-volume curves. No graphs for individual curves required.
    - **Option 2**: Curves are **overlaid** for both volume-time and flow-volume curves. Individual curves must be graphed separately, but are not required to meet ATS/ERS size standards.
    - **Option 3:** All curves are graphed **separately** at ATS/ERS size standards (± 1 mm size variation acceptable).

11. Normal reference value set used (NHANES III)
12. Predicted, percent predicted and lower limit of normal (LLN) values

K. Electronic Spirometry Report Output (required after February 2018)

1. **Stores 2005 ATS/ERS parameters**: A spirometry data file that is formatted in CSV or XML. Formatting of electronic files must follow Table 8 of the *2005 ATS/ERS Standardisation of Spirometry*. **Additional required output parameters** are listed in the table below.
2. **Stores all maneuvers:** Does the spirometry system save all maneuvers that a patient performs during a test session? If no, what is the maximum number of maneuvers the system will save?

CWHSP Spirometry Data File Parameters	
Required Parameters for Transmission	
Miner ID	Unique coal miner Identifier (#)
Miner Name	
Data Type	E=expiratory (+) I=inspiratory (-)
Barometric Pressure	mmHG
Ambient Temperature	°C (this temperature is used for BTPS correction)
Relative Humidity	%
Deleted Maneuver	Yes or No
Acceptable Maneuver	Yes or No
Expiratory Plateau achieved	Yes or No
BTPS factor	x.xxx
Calibration Date	MM/DD/YYYY
Calibration Time	HH:MM
Calibration result	P=pass F=fail
Test Date	MM/DD/YYYY
Test Time	HH:MM
Technician ID	CWHSP technician identifier (#)
Maneuver Number	1, 2, 3, 4, 5, 6, 7, 8
Height	cm
Weight	kg
Sex	M=male F=female
Race	(to be defined)
Date of Birth	MM/DD/YYYY
Testing position	Standing=1, sitting=2
FVC	mL
Back Extrapolated Volume (Vext)	mL or above ATS limit error code (>150 mL)
FEV1	mL
FEV1/FVC Ratio	
FEV6	mL
FEV1/FEV6 Ratio	
Peak Expiratory Flow (PEF)	mL/sec
Forced expiratory time (FET)	sec
Time to PEF	ms
Original sampling interval	ms
Flow Data Points	mL/sec
Spirometer manufacturer	
Spirometer model	
Spirometer serial number	
Additional Helpful Information for Transmission (optional)	
FVC quality attribute	A, B, C,D, F
FEV1 quality attribute	A, B, C, D, F



Section 3 Program and Staff Information

L. Spirometry procedure manual (available in lab) ☒ Yes: mo/yr revised 2/2016 ..... ☐ Yes: mo/yr revised ____

M. Ongoing spirometry quality assurance program ☒ Yes: mo/yr revised 2/2016 ..... ☐ Yes: mo/yr revised ____

N. Height measurement device ☒ Stadiometer (brand) Accurate Measure ☐ Other ____

O. Weight measurement device ☒ Medical scale (brand) Accurate Measure ☐ Other ____

P. Name(s) of spirometry technologist(s) Copy of NIOSH approved spirometry certificate attached?

Jane Jones ☒ Yes ____ ☐ Yes

Sally Smith ☒ Yes ____ ☐ Yes

Q. I agree to participate in this program in the manner specified by Part 37 of the Code of Federal Regulations (42 CFR Part 37), and understand that all information used in connection with this program will be held STRICTLY CONFIDENTIAL and divulged only as specified by the above Regulation.

Supervising Clinician Name (copy of license attached)	Signature	Date
John Leonard, MD	John Leonard	3/29/2016

Clinician certification or specialized spirometry training institution	Title+ Date of course or certification	Clinician Email
Spirometry Training Institute	Spirometry Training 1 - 11/20/2012	JLmd@city.net

CDC NIOSH 2.14 Rev 06/2014

Public reporting burden of this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-74, Atlanta, GA, 30333, ATTN: PRA (0920-0020).

Save Form | Email Form | Print Form | Reset Form | Date Form Generated

Section 3: Complete the following:

L. Spirometry procedure manual: The manual should include all equipment settings, equipment calibration check procedures, troubleshooting procedures for equipment failure, testing procedures, a sample test report, equipment maintenance and cleaning instructions, a copy of the spirometer's operating manual, a vendor list with contact information to order supplies, and infection control procedures.

M. Ongoing spirometry quality assurance program: The program should have one staff member with advanced spirometry training, who reviews test quality and provides feedback to technicians on a regular basis. Documentation should be made available upon request.

N. Height measurement device: height and weight must be measured without shoes

O. Weight measurement device: both height and weight must be measured

P. Name(s) of spirometry technician(s): Spirometry technicians must have a current NIOSH-approved Spirometry Certificate and must include an attached copy with the Clinic Application Form. This certificate is given to technicians who attend a NIOSH-approved Spirometry Training Course. This link http://www.cdc.gov/niosh/topics/spirometry/training.html takes you to information about the NIOSH Spirometry Training Course. A current course schedule link is included on that page. Please note that this requirement is written in the federal regulations (CFR 42 Part 37.9).

Q. Supervising Clinician information: The supervising clinician must have a medical license to:

1) Diagnose disease
2) Interpret medical test results
3) Offer medical treatment for individuals with disease or symptoms of disease

Additionally, this person must have specialized training in spirometry testing, which could be completion of a NIOSH, AMA, or ATS spirometry course, or be a licensed pulmonologist. A copy of the clinician's license and specialized spirometry training information must be included.

Spirometer Specifications:

Spirometers used in the CWHSP must meet 2005 ATS/ERS Standards for minimum accuracy, precision, and range of measurement as described in Table 6 of the 2005 ATS/ERS Standards seen below:

TABLE 6 Range and accuracy recommendations specified for forced expiratory manoeuvres

Test	Range/accuracy (BTPS)	Flow range $L \cdot s^{-1}$	Time s	Resistance and back pressure	Test signal
VC	0.5–8 L, ±3% of reading or ±0.050 L, whichever is greater	0–14	30		3-L Calibration syringe
FVC	0.5–8 L, ±3% of reading or ±0.050 L, whichever is greater	0–14	15	<1.5 $cmH_2O \cdot L^{-1} \cdot s^{-1}$ (0.15 $kPa \cdot L^{-1} \cdot s^{-1}$)	24 ATS waveforms, 3-L Cal Syringe
FEV_1	0.5–8 L, ±3% of reading or ±0.050 L, whichever is greater	0–14	1	<1.5 $cmH_2O \cdot L^{-1} \cdot s^{-1}$ (0.15 $kPa \cdot L^{-1} \cdot s^{-1}$)	24 ATS waveforms
Time zero	The time point from which all FEV_t measurements are taken			Back extrapolation	
PEF	Accuracy: ±10% of reading or ±0.30 $L \cdot s^{-1}$ (20 $L \cdot min^{-1}$), whichever is greater; repeatability: ±5% of reading or ±0.15 $L \cdot s^{-1}$ (10 $L \cdot min^{-1}$), whichever is greater	0–14		Mean resistance at 200, 400, 600 $L \cdot min^{-1}$ (3.3, 6.7, 10 $L \cdot s^{-1}$) must be <2.5 $cmH_2O \cdot L^{-1} \cdot s^{-1}$ (0.25 $kPa \cdot L^{-1} \cdot s^{-1}$)	26 ATS flow waveforms
Instantaneous flows (except PEF)	Accuracy: ±5% of reading or ±0.200 $L \cdot s^{-1}$, whichever is greater	0–14		<1.5 $cmH_2O \cdot L^{-1} \cdot s^{-1}$ (0.15 $kPa \cdot L^{-1} \cdot s^{-1}$)	Data from manufacturers
$FEF_{25-75\%}$	7.0 $L \cdot s^{-1}$, ±5% of reading or ±0.200 $L \cdot s^{-1}$, whichever is greater	±14	15	Same as FEV_1	24 ATS waveforms
MVV	250 $L \cdot min^{-1}$ at V_T of 2 L within ±10% of reading or ±15 $L \cdot min^{-1}$, whichever is greater	±14 (±3%)	12–15	<1.5 $cmH_2O \cdot L^{-1} \cdot s^{-1}$ (0.15 $kPa \cdot L^{-1} \cdot s^{-1}$)	Sine wave pump

BTPS: body temperature and ambient pressure saturated with water vapour; VC: vital capacity; FVC: forced vital capacity; ATS: American Thoracic Society; FEV_1: forced expiratory volume in one second; FEV_t: forced expiratory volume in t seconds; PEF: peak expiratory flow; $FEF_{25-75\%}$: mean forced expiratory flow between 25% and 75% of FVC; MVV: maximum voluntary ventilation; V_T: tidal volume.

The spirometer also must be able to do the following:

1. Back extrapolation volume must be able to be determined for each maneuver with an error alert if back extrapolation > 150 ml
2. Flow type spirometers must define 'end-of-test' criteria as less than 25 ml for one or more seconds, or an average of less than 25 ml over 2 seconds.
3. The spirometer must electronically save and recall results and spirometry flow-volume (F/V) and volume-time (V/T) curves from at least three 'best' maneuvers. Storage for all maneuvers is preferred, but it is mandatory that at least 8 maneuvers are able to be saved for each test session.
4. The spirometer can 'ghost out', 'shadow' or 'hide' erroneous trials.
5. All spirometry values are reported at BTPS

NIOSH CWHSP Customized Report Format

This is a list of information that must be included in CWHSP spirometry test reports. The pages must be printed at 100% in order to correctly match the size of facility graphs with sample graphs at 2005 ATS Standards. There must be **at least 3 acceptable maneuvers** reported. Volume-time and flow volume graphs **for each maneuver** must be on the report. Again, please note that the pages must be printed at 100% in order to match or exceed the graph sizes.

Provide a sample test report from each unit that includes all the following information.

1. Clinic name, facility approval number, city, state, zip code
2. Miner's name and medical record number
3. Miner's age, sex, race, height, and weight
4. Miner position during testing (standing or sitting)
5. Room temperature, barometric pressure
6. Spirometer serial number or identification number
7. Dates and time of test and last calibration check
8. Numerical values for all attempted trials [FVC, FEV6, FEV1, FET, PEF, (FEV1/FVC, FEV1/FEV6 – calculated from highest values)] and back extrapolated volume is strongly recommended (as volume, not percent). Common abbreviations: V_{ext}, BEV, EV.
9. Test repeatability for FVC and FEV1
10. Unacceptable and maneuver error codes should be clearly identified when reporting maneuvers
11. Volume-time and flow-volume graphs for all attempted trials must be reported in one of these three format options:
    - **Option 1**: Curves are **staggered** at ATS/ERS size standards (± 1 mm size variation acceptable) for both volume-time and flow-volume curves. No graphs for individual curves required.
    - **Option 2**: Curves are **overlaid** at ATS/ERS size standards (± 1 mm size variation acceptable) for both volume-time and flow-volume curves. Individual curves must be graphed separately, but are not required to meet ATS/ERS size standards.
    - **Option 3**: All curves are graphed **separately** at ATS/ERS size standards (± 1 mm size variation acceptable).
12. If no plateau on volume-time curves, graph must extend greater than 15 seconds. Otherwise, if there is a one-second plateau on volume-time curves, graph must extend to the next second after the expiratory plateau
13. Normal reference value set used (NHANES III)
14. Predicted, percent predicted and lower limit of normal values

Checklist of documents to include with your NIOSH Spirometry Facility Certification Form

- ☐ Application form: all fields completed
- ☐ Spirometer validation letter
- ☐ Test report sample: test report for interpreter, all graphs at correct sizes and formats (i.e. staggered, overlaid, or individual graphs), numerical values for all attempted trials. *See detailed instructions for test reports in this document*. A calibration report is also preferred.
- ☐ NIOSH approved spirometry certificates from testing clinicians (current)
- ☐ Supervising Clinician: copy of license and specialized spirometry training

Sample Test Report: The following pages are a sample test report to use as a guide when selecting printed test report settings on your spirometer.

NIOSH Sample Spirometry Report

CWHSP Clinic Name
4141 No Name Street
Utopia, WY XXXXX-XXXX
CWHSP Facility ID: XXXXX

Miner Name:
DOB
Age:
Sex
Height (in):
Weight (lbs):
Race:
Smoker:
Comments:

Test Date: XX/XX/XXXX xx:xx:xx
Calibration Date/Time: XX/XX/XXXX xx:xx:xx
Spirometry Model: Serial#:
Barometric (mmHg): BTPS:
Ambient Temp (C°): RH (%) :
Predictive Ref: NHANESIII
Testing Technician:
Testing Position:

Parameter	Pred	LLN	Best	%Pred	Trial1	Trial2	Trial3
FVC (L)	X.XX	X.XX	X.XX	XX.X	X.XX	X.XX	X.XX
FEV1 (L)	X.XX	X.XX	X.XX	XX.X	X.XX	X.XX	X.XX
FEV1/FVC (%)	X.XX	X.XX	X.XX	XX.X	X.XX	X.XX	X.XX
$FEF_{25\%-75\%}$ (L)	X.XX	X.XX	X.XX	XX.X	X.XX	X.XX	X.XX
FEV6 (L)	X.XX	X.XX	X.XX	XX.X	X.XX	X.XX	X.XX
FEV1/FEV6 (%)	X.XX	X.XX	X.XX	XX.X	X.XX	X.XX	X.XX
PEF (L/sec)	X.XX	X.XX	X.XX	XX.X	X.XX	X.XX	X.XX
FET (sec)					X.XX	X.XX	X.XX
Vext (L)					X.XX	X.XX	X.XX

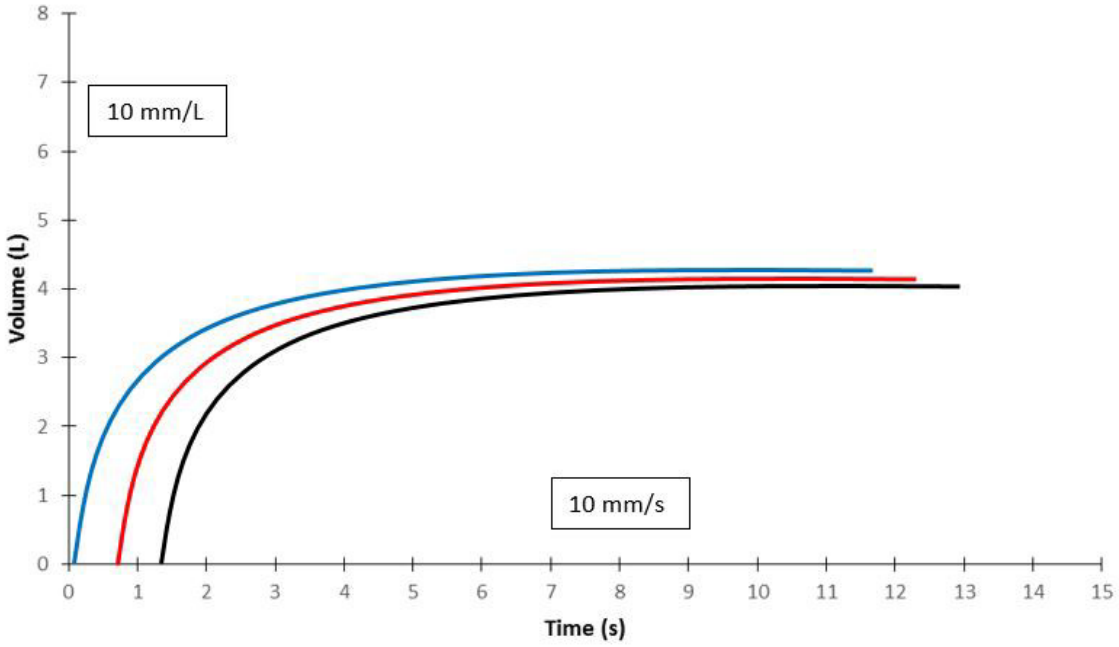
* Trial used for Best; Acceptability (FEV1 var= x.xxL (X.X %); FVC var=x.xxL (X.X%)

Physician Interpretation

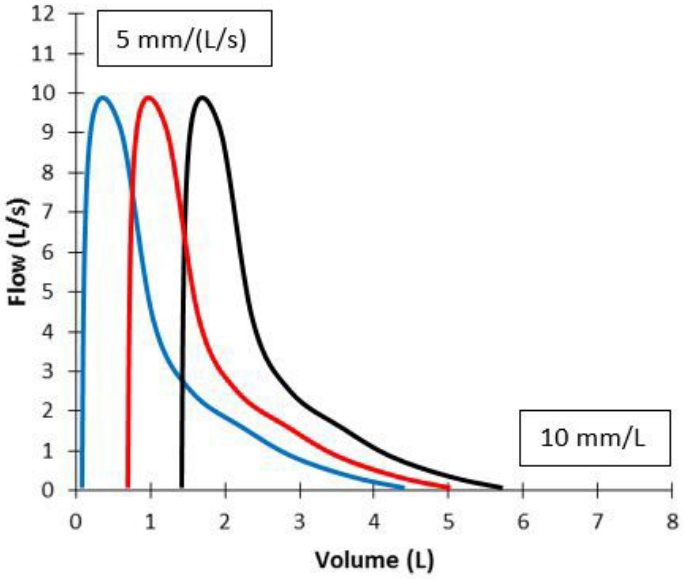
Signature _____ Date XX/XX/XXXX

Option 1: Curves are staggered at ATS size standards, no need for individual graphs

FVC Volume-Time Graphical Output (Staggered)

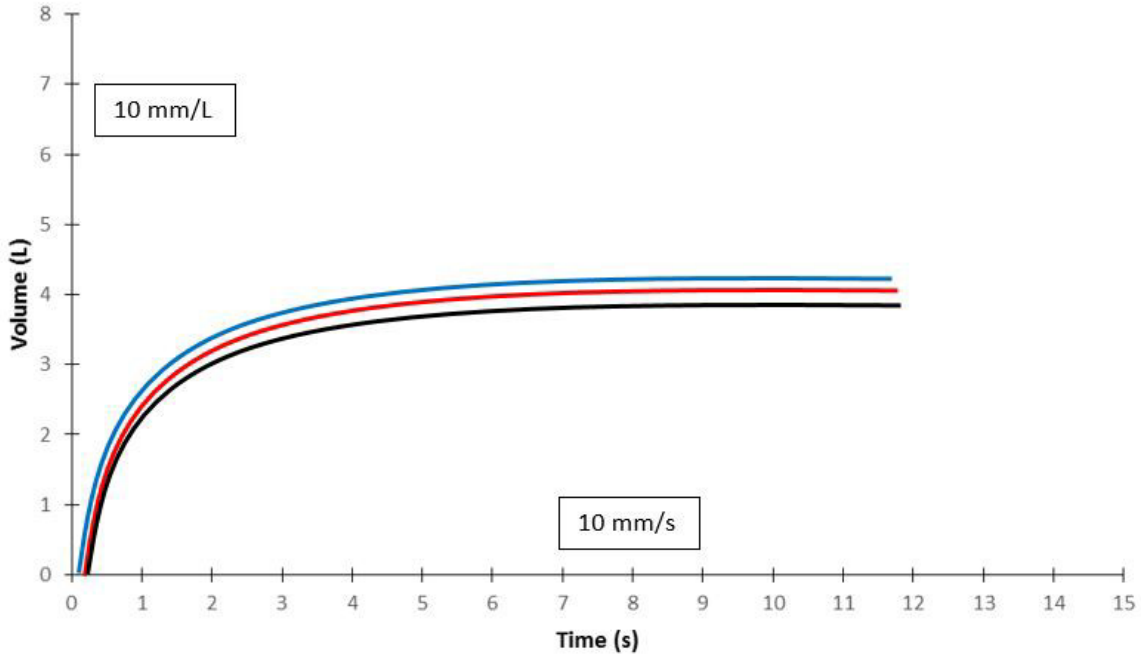


FVC Flow-Volume Graphical Output (Staggered)

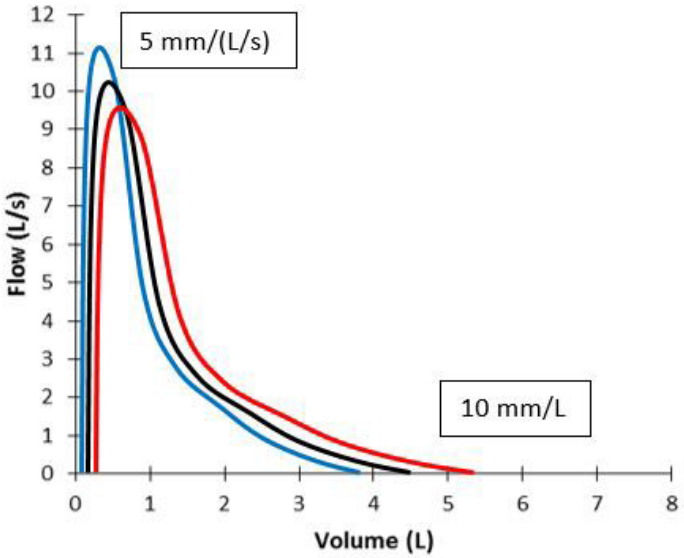


Option 2: Curves are overlaid at ATS size standards, individual curves graphed separately

FVC Volume-Time Graphical Output (Overlaid)

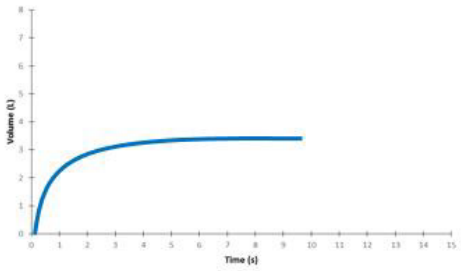


FVC Flow-Volume Graphical Output (Overlaid)

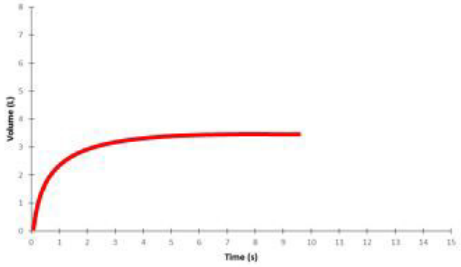


Option 2 Continued: Individual curves not required to meet ATS size standards

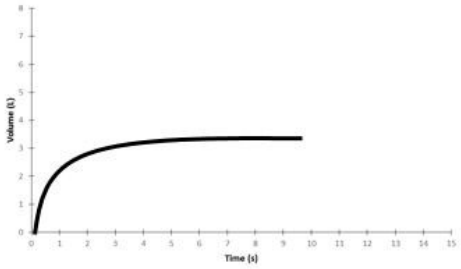
Trial 1:



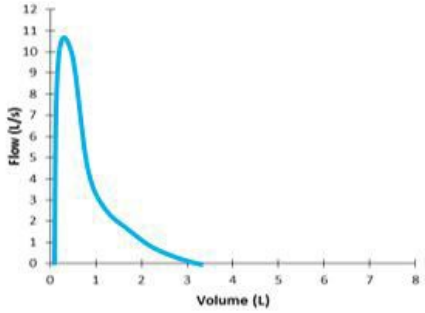
Trial 2:



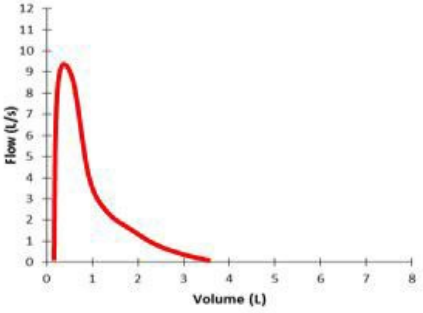
Trial 3:



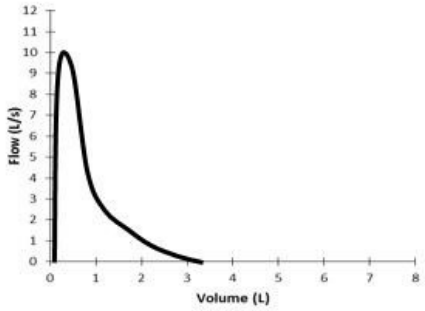
Trial 1:



Trial 2:



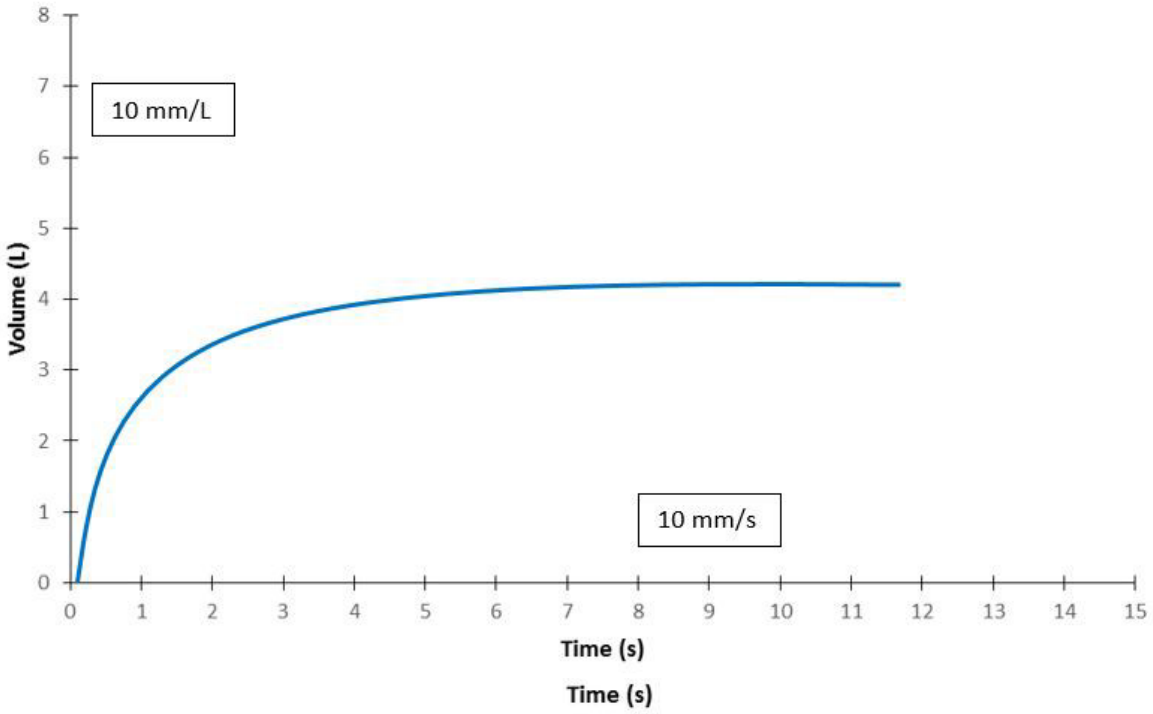
Trail 3:



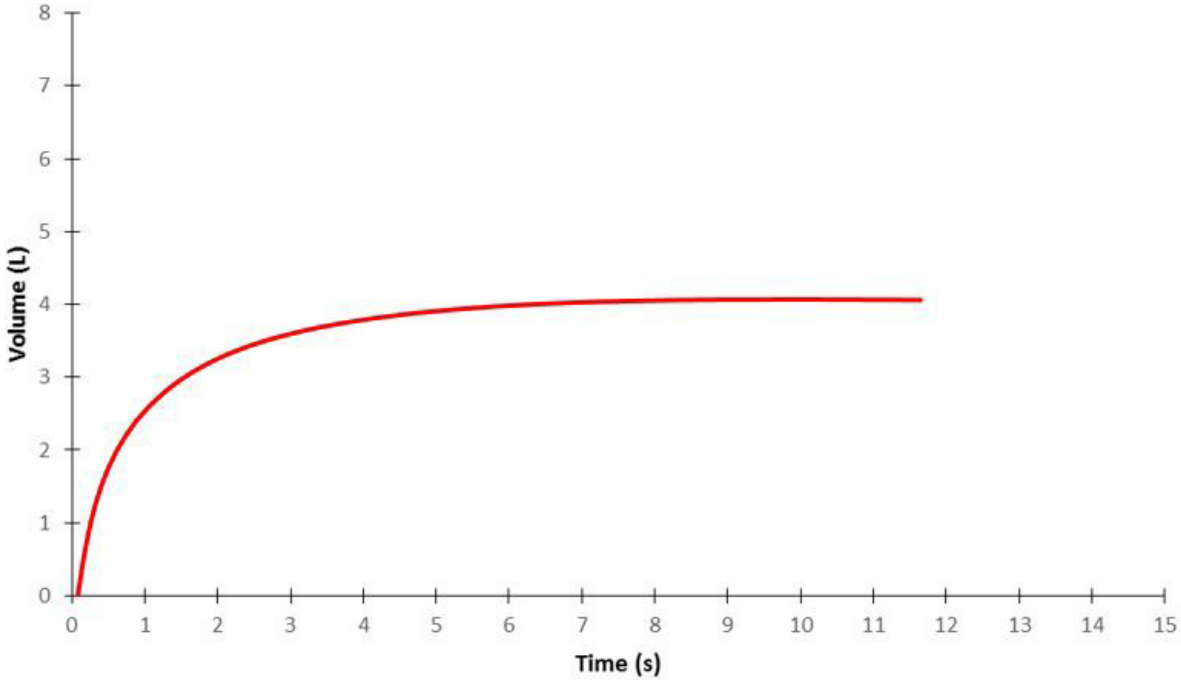
Option 3: All curves graphed separately at ATS size standards

FVC Volume-time Curves Graphed Separately

Trial 1:

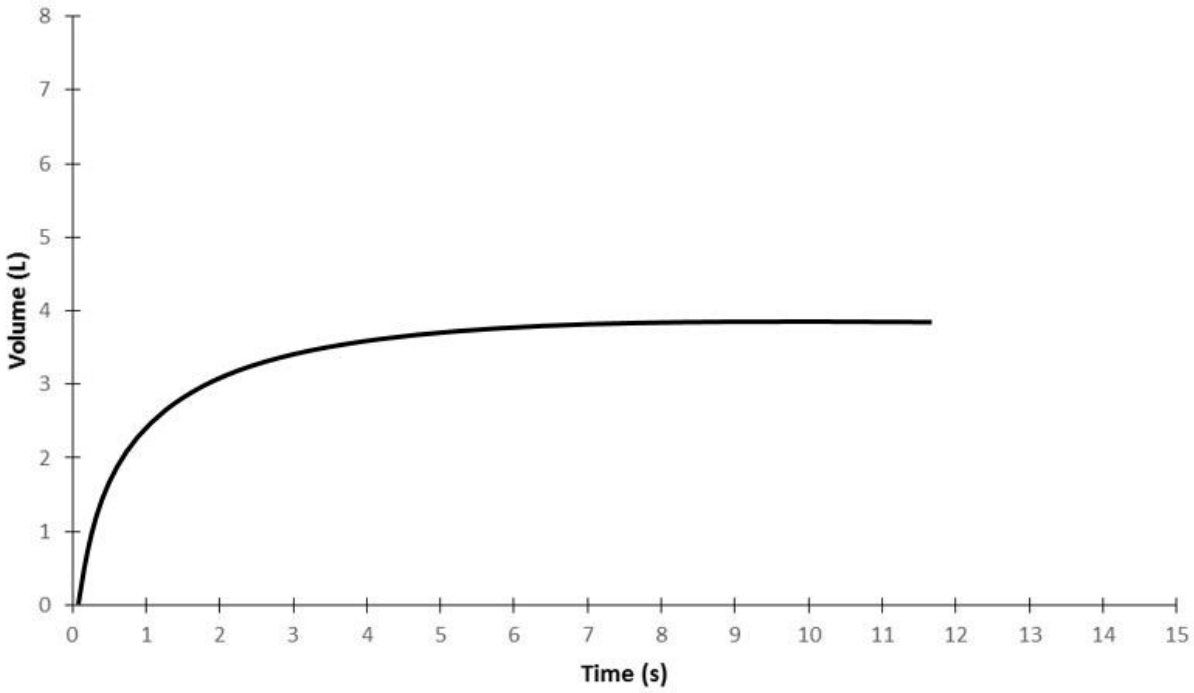


Trial 2:



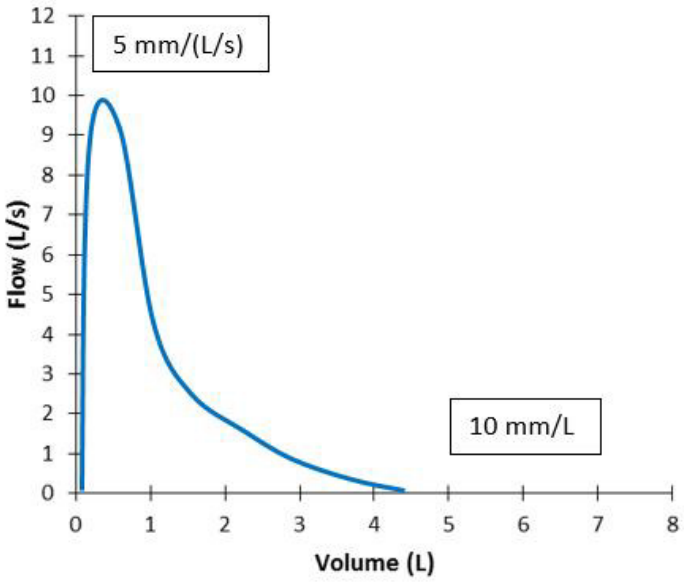
Option 3 Continued:

Trial 3:



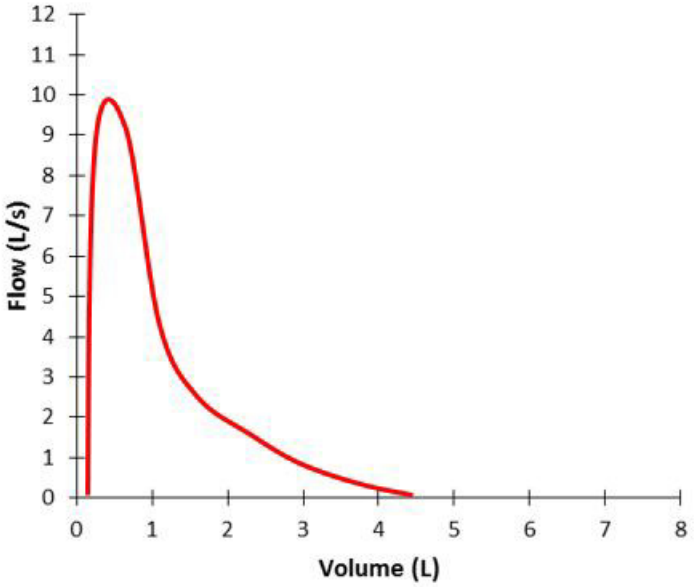
FVC Flow-Volume Graphed Separately

Trial 1:

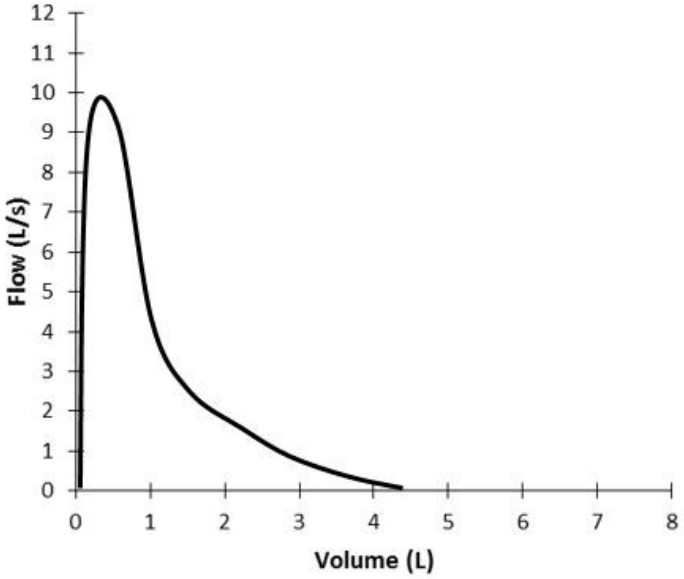


Option 3 Continued:

Trial 2:



Trial 3:



Three Liter Syringe Calibration:

Calibration Date: XX/XX/XXXX Time: XX:XX Ambient Temperature (C°):XX Barometric Pressure (mmHg): XXX
Serial Number:
Calibrated by:

	Syringe Volume (L)	Injection1	Injection 2	Injection 3
		Measured	Measured	Measured
FVC (L)	3.00	X.XX	X.XX	X.XX
PEF (L/S)		XX.XX	XX.XX	XX.XX

Examples of Flow vs. Volume and Volume vs. Time Calibration Printouts: