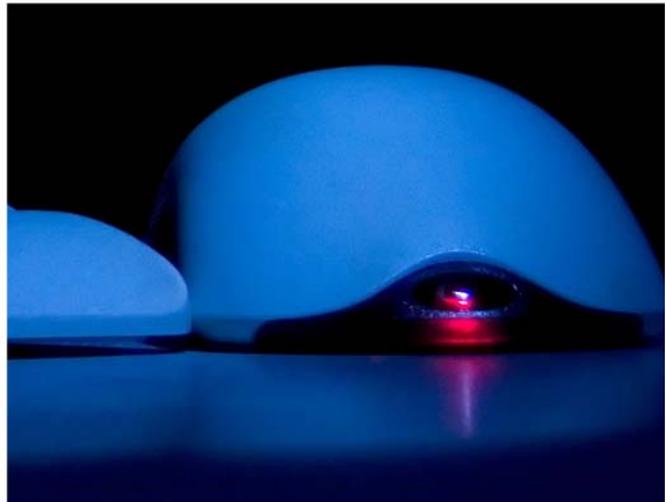
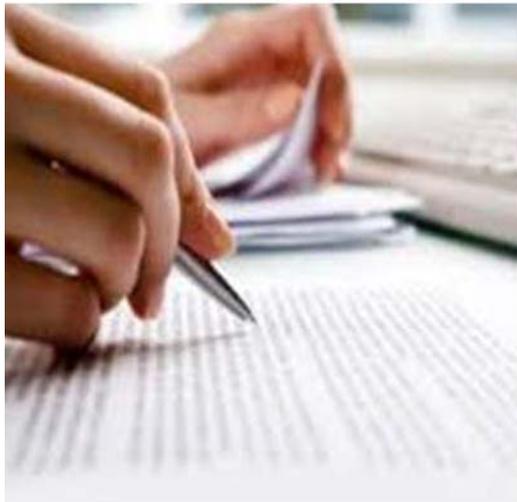
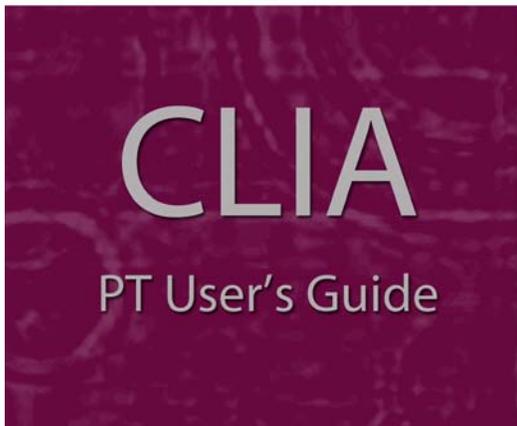


# CLIA Proficiency Testing User's Guide



Information in this user guide is subject to change without notice.

All brand or product names are trade names, service marks, trademarks, or registered trademarks of their respective companies or organizations.

---

**Note:** This document can be viewed online or printed in a duplex (two-sided) format. Blank pages have been automatically inserted as needed for correct pagination in the printed copy.

---

# Contents

- Introduction ..... 5**
  - About this User’s Guide ..... 5**
    - View this Document Online..... 6
    - View a Printed Copy of this Document..... 6
  - Accessibility ..... 7**
- CLIA Proficiency Testing Specifications ..... 9**
  - File Processing ..... 9**
  - Submission Record Layouts..... 9**
    - Header Record..... 9
    - Enrollment Record..... 10
    - Score Record..... 11
    - Trailer Record ..... 12
  - Response Record Layouts..... 13**
    - Statistics Record (Informational)..... 13
    - Plug Hole Information..... 15
    - Error Record..... 17
  - Batch Edits ..... 18**
    - File Submission Edits..... 18
    - Common Edits ..... 18
    - Enrollment Edits ..... 19
    - Score Edits..... 20
  - Analytes ..... 20**
  - Help Desk ..... 23**
- PT Upload ..... 25**
  - Accessing PT Upload..... 25**
  - PT Upload Navigation ..... 27**
  - File Upload ..... 28**
  - File Download..... 31**
  - Help..... 35**
    - Accessibility Policy..... 36
    - Contact Us ..... 36
    - Privacy Policy ..... 37
- Terminology ..... 39**



# Introduction

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The final CLIA regulations were published in the Federal Register on February 28, 1992. The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April, 24, 2003.

Proficiency Testing (PT) is the testing of unknown samples sent to a laboratory by a CMS-approved PT Program. Most sets of PT samples are sent to participating laboratories three times per year. After testing the PT samples in the same manner as its patient specimens, the laboratory reports its sample results back to its PT Program. The Program grades the results using the CLIA grading criteria and sends the laboratory scores reflecting how accurately it performed the testing. CMS and accreditation organizations routinely monitor their laboratories' performance.

## About this User's Guide

This *CLIA Proficiency Testing User's Guide* is intended for use primarily by PT Program personnel. It consists of this introduction and the following three chapters:

- CLIA Proficiency Testing Specifications  
Describes PT Program file processing and presents file specifications.
- PT Upload  
Provides procedures for using the PT Upload component of the ASPEN Web CLIA Maintenance system to upload PT testing results and review the uploaded files as well as the Error and Statistics files created when the PT files are processed. Shows and describes PT Upload screens and dialog boxes.
- Terminology  
Defines relevant terms.

## View this Document Online

You must have Adobe Reader installed to view this document online. You can download the latest version from <http://www.adobe.com/products/acrobat/readstep2.html>.

On any page, you can click the Increase (+) or Decrease (-) button in the toolbar to adjust the page magnification to your comfort level. Use the bookmarks in the left pane of Adobe Reader to locate and go (click the bookmark) to relevant information in this user guide.

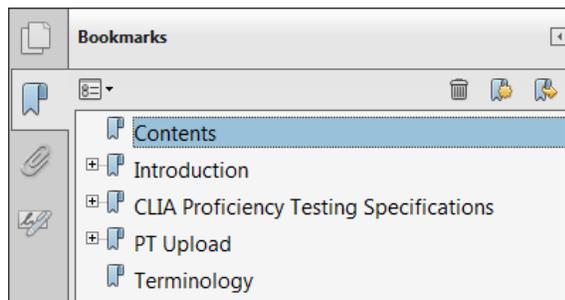


Figure 1: Bookmarks

You can also click the Contents bookmark and then click links in the table of contents to go to relevant topics.

---

**TIP:** For best viewing quality in Adobe Reader, go to Edit | Preferences | Page Display (path may vary somewhat depending on version). Select the applicable Smooth Text option.

---

A link (cross-reference) to additional material appears as follows. Click the link to directly access the related information.

**More ...**

["PT Upload" on page 25](#)

## View a Printed Copy of this Document

While it is designed to be used easily online, you can print this document if you prefer. If you print this user guide, refer to the Table of Contents to locate the information you need. Links (cross-references) to additional material in this document include page numbers; simply go to the indicated page.

## Accessibility

This *CLIA Proficiency Testing User's Guide* includes a number of 508-compliant accessibility features, as detailed below.

- Alternative text (alt text), which screen readers can read, is defined for all graphics.
- All graphics have captions.
- Information is not conveyed by means of color alone.
- Tables are generally not used for formatting, so text is accessible to screen readers.
- Windows keyboard shortcuts are included.
- Reading order is optimized, so content is read correctly by screen readers.



# CLIA Proficiency Testing Specifications

## File Processing

PT Programs submit testing results for processing using the PT Upload application. The files are processed on Thursday evenings and output is available for download the following day. Files are submitted using fixed format text files that have a .TXT extension, and meet the specifications provided in this document. CDC gets a mirror copy of the input, output statistics, and output error files.

Due to the large volume of data, an archive process moves data that is five years or older to history files. The archive occurs in August.

The analyte table is updated when new analytes are added or existing ones removed. The current version is included in this document.

**More ...**

["PT Upload" on page 25](#)

## Submission Record Layouts

A PT Program submits files to be processed on a weekly basis. If multiple files are submitted, each file must contain a unique batch date in the header record. The submitted files must meet the following fixed format specifications, and will be processed if they pass all file submission edits.

### Header Record

Field Name	Start	End	Length	Type	Description
RECORD.TYPE	1	1	1	A	Type of record – must be H for header record
BATCH.DT	2	9	8	N	Batch date in format CCYYMMDD
PROGRAM.NUM	10	12	3	N	PT Program identification number assigned by CMS. Left pad with 0's.

## Enrollment Record

This record contains information on the enrollment of laboratories in your PT Program. The record must meet all Common and Enrollment edits before it will be processed.

One record should be sent for each test requiring PT that a laboratory performs in a given test year. The record length is 80 bytes and is a fixed length record.

Field Name	Start	End	Length	Type	Description
RECORD.TYPE	1	1	1	A	Type of record – must be P for enrollment record.
PROV.NUM	2	11	10	A	CLIA number assigned to laboratory by CMS. Format is 10 characters with a D in the 3 <sup>rd</sup> position.
TEST.YR	12	15	4	N	Calendar year in which the enrollment applies. Format is CCYY.
ANALYTE.ID	16	19	4	N	Analyte test identification number.
ACTION.TYPE	20	20	1	N	Type of action. (1=Delete, 2=Add, 3=Correction)
RECORD.SEQ.NUM	21	27	7	N	One up sequence number for each record in the batch.
EFF.DT	28	35	8	N	Date the laboratory enrolled with the PT Program. Format CCYYMMDD
SUBMSN.DT.1	36	43	8	N	PT score submission date for event number 1. Format CCYYMMDD. *
SUBMSN.DT.2	44	51	8	N	PT score submission date for event number 2. Format CCYYMMDD. *
SUBMSN.DT.3	52	59	8	N	PT score submission date for event number 3. Format CCYYMMDD. *
FILLER	60	80	21	A	Blanks to set record length to 80 characters.

\*The PT score submission dates supplied in the enrollment record should be 60 days after the date when the PT Program is to receive the results back from the laboratory.

## Score Record

This record contains information on the scores your PT Program is reporting for a laboratory's routine and non-routine testing. The record must meet all Common and Score edits before it will be processed.

There will be one record for each PT score (percent of correct challenges). The record length is 80 bytes and is a fixed length record.

Field Name	Start	End	Length	Type	Description
RECORD.TYPE	1	1	1	A	Type of record – must be S for score record.
PROV.NUM	2	11	10	A	CLIA number assigned to laboratory by CMS. Format is 10 characters with a D in the 3 <sup>rd</sup> position.
TEST.YR	12	15	4	N	Calendar year in which the score applies. Format is CCYY.
ANALYTE.ID	16	19	4	N	Analyte test identification number.
EVENT.NUM	20	20	1	N	Event number of the score (0=Non-routine, 1=Event #1, 2=Event #2, 3=Event #3).
ACTION.TYPE	21	21	1	N	Type of action code (1=Delete, 2=Add, 3=Correction).
RECORD.SEQ.NUM	22	28	7	N	One up sequence number for each record in the batch.
SUBMSN.DT	29	36	8	N	Submission date for this score, must correspond to the submission dates supplied in the enrollment record. Format CCYYMMDD.
SCORE.NUM	37	39	3	N	Score received by the laboratory. Value from 0 to 100.
REASON.CD.1	40	41	2	N	Reason code provided for a score of 0 or 100. *
REASON.CD.2	42	43	2	N	Reason code provided for a score of 0 or 100. *
REASON.CD.3	44	45	2	N	Reason code provided for a score of 0 or 100. *
REASON.CD.4	46	47	2	N	Reason code provided for a score of 0 or 100. *
REASON.CD.5	48	49	2	N	Reason code provided for a score of 0 or 100. *
FILLER	50	80	31	A	Blanks to set record length to 80 characters.

## \* Reason Codes:

Code	Description	Associated Score must be 0 (edit S-103)	Count as Failure	Count toward Group Score
0	Change to waived method	Yes	No	No
1	Failure to participate	No	Yes	Yes
2	Failure to participate, exclusion requested	No	N/A (100%)	Yes
3	Untimely return of results	No	Yes	Yes
4	Ungradable	No	N/A (100%)	Yes
5	Test not performed, would refer	No	N/A (100%)	Yes
6	Result variance	No	Yes	Yes
7	Method/Instrument not stated	No	Yes	Yes
8	Multiple survey averaged score	No	Yes	Yes
9	Test not performed, not offered	Yes	No	No
10	Natural disaster/emergency - excused participation	No	N/A (100%)	Yes

## Trailer Record

Each submitted file must contain a trailer record to ensure a complete file was transmitted.

Field Name	Start	End	Length	Type	Description
RECORD.TYPE	1	1	1	A	Type of record – must be T for trailer record.
TRANS.COUNT	2	8	7	N	Number of records in the batch file including the header and trailer records.

## Response Record Layouts

PT Programs submit PT scores weekly via the PT Upload application. Three types of response records are produced when the files are processed:

- Statistics
- Plug Hole
- Error

They are described in the following sections.

### More ...

["PT Upload" on page 25](#)

## Statistics Record (Informational)

This file will be produced by the PT upload process and will be available for download on Friday via the PT Upload application. It should be reviewed by the PT Program after the data has been loaded into the CMS/PT system. Record length will be 80 bytes. The message will give summary statistics, such as total number of ENROLLMENT or SCORES records read, written, etc.

The first line is the header, which is formatted as follows:

Field Name	Start	End	Length	Type	Description
Spaces	1	8	8		Spaces
H	9	9	1	A	H
Batch Date	10	17	13	N	Date in format YYYYMMDD.
PT Program	18	20	3		PT Program

The following lines contain the record count and description, formatted as follows:

Field Name	Start	End	Length	Type	Description
STAT-TOTAL-RECORDS	1	7	7	N	Number of Records Processed (left padded with zeros).
FILLER	8	8	1		Filler (space).
STAT-MESSAGE	9	80	72	A	Description of Statistics.*

\*Description of Statistics:

- TOTAL PROFICIENCY TESTING RECORDS IN THIS UPDATE
- TOTAL ERROR MESSAGES GENERATED FOR THIS UPDATE
- TOTAL WARNING MESSAGES GENERATED FOR THIS UPDATE
- TOTAL ENROLLMENT TRANSACTIONS PROCESSED
- TOTAL ENROLLMENT RECORDS ADDED
- TOTAL ENROLLMENT RECORDS CORRECTED
- TOTAL ENROLLMENT RECORDS DELETED
- TOTAL ENROLLMENT TRANSACTIONS REJECTED
- TOTAL SCORES TRANSACTIONS PROCESSED
- TOTAL SCORES RECORDS ADDED
- TOTAL SCORES RECORDS CORRECTED
- TOTAL SCORES RECORDS DELETED
- TOTAL SCORES TRANSACTIONS REJECTED

**Example Statistics File**

```
H20100405001
0047398 RECORDS READ IN
0000000 TOTAL ERROR MESSAGES GENERATED FOR THIS UPDATE
0000000 TOTAL WARNING MESSAGES GENERATED FOR THIS UPDATE
0023698 ENROLL TRANSACTIONS PROCESSED
0023698 SCORE TRANSACTIONS PROCESSED
0000000 TRANSACTION RECORDS REJECTED
0023650 ENROLLMENT RECORDS ADDED
0000000 ENROLLMENT RECORDS CORRECTED
0000000 ENROLLMENT RECORDS DELETED
0023698 ENROLLMENT TRANSACTIONS PROCESSED
0000048 ENROLLMENT TRANSACTIONS REJECTED
0023650 SCORES RECORDS ADDED
0000000 SCORES RECORDS CORRECTED
0000000 SCORES RECORDS DELETED
0023698 SCORES TRANSACTIONS PROCESSED
0000048 SCORES TRANSACTIONS REJECTED
```

## Plug Hole Information

For each event, there will be a section to report on each of the three exceptions. The sections will be titled as follows:

- SCORE WITH NO MATCHING ENROLLMENT (Informational)
- ENROLLMENT WITH BLANK SCORE SUBMISSION DATE (Warning)
- ENROLLMENT WITH NO SCORE (Error)

For each exception the following is displayed (with a single space between each field):

- PT Program # (pt\_pgm\_id)
- CLIA number (prvdr\_num)
- Analyte # (analyte\_id)
- PT Score Submission Date for the current event in YYYYMMDD format
- Test Year (test\_yr\_num)
- Event # (event\_num)

The following Summary information is calculated and written at the end of each event being reported:

ORG	3 digit PT Program #.
ENRL	Total number of Enrollment or Score records for the event being reported.
MATCH	Total number of Enrollment records that have matching score records for the event being reported on PLUS number of active Score records (i.e. have a matching Enrollment record).
NO MATCH	Total number of Enrollment records that do not have a matching Score record for the event being reported PLUS number of "R"emoved Score records (i.e., do not have a matching Enrollment record).
=	Divide NO MATCH by MATCH to get a percentage. Shown to two levels of precision.

The formatting is the same as the legacy Plug Hole Report where there is a section for each of the three events ordered by the Provider Number.

### Example Plug Hole Report

PROCESSING PLUGHOLE ON 02/19/2013

PT MISSING SCORES FOR TEST YEAR 2012 SECOND EVENT COMPARE

SCORE WITH NO MATCHING ENROLLMENT (Informational)

013 18D0325208 0285 20120814 2012 2

013 52D0923361 0115 20120805 2012 2

ENROLLMENT WITH BLANK SCORE SUBMISSION DATE (Warning)

ENROLLMENT WITH NO SCORE (Error)

ORG = 013 ENRL = 00016600 MATCH = 00016600 NO MATCH = 00000000 = 0.00%

PT MISSING SCORES FOR TEST YEAR 2012 THIRD EVENT COMPARE

SCORE WITH NO MATCHING ENROLLMENT (Informational)

ENROLLMENT WITH BLANK SCORE SUBMISSION DATE (Warning)

ENROLLMENT WITH NO SCORE (Error)

013 15D0360690 0865 20121216 2012 3

013 49D0223176 0615 20121127 2012 3

013 52D1075632 0405 20121127 2012 3

ORG = 013 ENRL = 00016644 MATCH = 00016607 NO MATCH = 00000003 = 0.02%

PT MISSING SCORES FOR TEST YEAR 2013 FIRST EVENT COMPARE

SCORE WITH NO MATCHING ENROLLMENT (Informational)

ENROLLMENT WITH BLANK SCORE SUBMISSION DATE (Warning)

ENROLLMENT WITH NO SCORE (Error)

ORG = 013 ENRL = 00000000 MATCH = 00000000 NO MATCH = 00000000 = 0.00%

## Error Record

This file is written by the PT upload process when an error is detected in a record transmitted by a PT Program. Record length is 80 bytes. The message describes the detected error.

Field Name	Start	End	Length	Type	Description
EDIT NUMBER	1	5	5	N	
RECORD SEQ NUM	7	13	7	N	Record batch sequence # provided by PT Program (padded with zeros)
FIELD NAME	15	34	20	A	Field name
ERR MESSAGE	36	80	45	A	Error message

If the file is processed (i.e., no file submission errors), the following totals are displayed at the end of the file:

- TOTAL PROFICIENCY TESTING RECORDS IN THIS UPDATE  
Total number of enrollment and score records processed (read in).
- TOTAL ERROR MESSAGES GENERATED FOR THIS UPDATE  
Total number of enrollment and score records that were not processed due to edit errors.
- TOTAL WARNING MESSAGES GENERATED FOR THIS UPDATE  
Total number of enrollment and score records that were processed, but that produced an edit warning message (warning messages will display in the error file).

### Example Error File

```
P.T. # 001 BATCH DATE = H20100405
ERROR & WARNING SYNOPSIS FOR THIS UPDATE AS OF 04/12/2010
```

```
E-102 0001047 EFCTV_DTThe enrollment effective date must
be on or after the date when PT Program was approved for testing
(mm/dd/yyyy).
```

```
...
```

```
TOTAL PROFICIENCY TESTING RECORDS IN THIS UPDATE = 0047398
TOTAL ERROR MESSAGES GENERATED FOR THIS UPDATE = 0000096
TOTAL WARNING MESSAGES GENERATED FOR THIS UPDATE = 0000000
```

## Batch Edits

This section covers the edits enforced when processing a submitted file. If any file submission errors are found, the file is not processed. Users will be notified of all file submission errors at the time the file is submitted using the PT Upload application. Other errors will be written to the error file during processing and will be available for download on Friday.

### File Submission Edits

<b>Edit #</b>	<b>Error Message</b>
H-100	First record in the submitted file is not a valid header record.
H-101	Batch date CCYYMMDD cannot be submitted, must be after CCYYMMDD and a date that has not already been submitted.
H-102	Invalid PT Program ID in the header record.
H-103	Current user does not have permission to load files for PT Program #X.
H-104	Batch date submitted in the header record (CCYYMMDD) is invalid.
H-105	Batch date cannot be a future date.
H-106	A file with batch date has already been submitted and processed.
H-107	No trailer record, file not accepted.
H-108	Trailer record contains an invalid record count, value must be numeric and match the number of transactions sent in the file. (Note – in M204 this is a warning but decision made to make this a hard edit in Aspen and not process the file if the trailer record is incomplete).
H-109	More than one header record included in the file.

### Common Edits

These edits apply to both enrollment and score records.

<b>Edit #</b>	<b>Error Message</b>
C-100	Record type must be present and be a valid type; H(Header), S(Score), P(Enrollment), T(Trailer).
C-101	Provider number is a required field.
C-102	Provider number X is not a valid CLIA ID.
C-103	The action type field must be a valid numeric value.
C-104	The sequence field must be a valid numeric value.

<b>Edit #</b>	<b>Error Message</b>
C-105	The test year field must be a valid year in CCYY format.
C-106	Test year cannot be before CCYY <cut off year>.
C-107	The test ID must be a valid non-group analyte value.
C-108	The test ID is not valid for the year CCYY and Program 000.
C-109	The CLIA laboratory number ##D##### is not valid.

## Enrollment Edits

<b>Edit #</b>	<b>Error Message</b>
E-100	The enrollment effective date is not a valid date.
E-101	The enrollment effective date must be within the test year.
E-102	The enrollment effective date must be on or after the date when PT Program was approved for testing (mm/dd/yyyy).
E-103	The enrollment effective date cannot be after the expiration date of the PT Program (mm/dd/yyyy).
E-104	The enrollment effective date is required.
E-105	At least one PT Score Submission date is required.
E-106	PT Score Submission Date 1 is an invalid date.
E-107	PT Score Submission Date 1 cannot be before the enrollment effective date of mm/dd/yyyy.
E-108	PT Score Submission Date 1 must be the same year as the test year (CCYY).
E-109	PT Score Submission Date 2 is an invalid date.
E-110	PT Score Submission Date 2 cannot be before the enrollment effective date of mm/dd/yyyy.
E-111	PT Score Submission Date 3 is an invalid date.
E-112	PT Score Submission Date 3 cannot be before the enrollment effective date of mm/dd/yyyy.
E-113	PT Score Submission Date 2 for analyte ### cannot be greater than test year (CCYY) plus one.
E-114	PT Score Submission Date 2 must be the same year as the test year (CCYY).
E-115	PT Score Submission Date 3 cannot be greater than test year (CCYY) plus one.
E-116	PT Score Submission Date 2 (CCYYMMDD) must be greater than PT Score Submission Date 1 (CCYYMMDD).
E-117	PT Score Submission Date 3 (CCYYMMDD) must be greater than PT Score Submission Date 2 (CCYYMMDD).
E-118	No enrollment record found to delete.

<b>Edit #</b>	<b>Error Message</b>
E-119	Warning: No enrollment record found to correct, system will add an enrollment record for this lab and analyte.
E-120	Warning: An enrollment record already exists for this lab and analyte. The existing record will be corrected.

## Score Edits

<b>Edit #</b>	<b>Error Message</b>
S-100	Event number is required and must be a valid value between 0 and 3.
S-101	The PT Score Submission Date is required and must be a valid date.
S-102	The score is required and must be a valid value between 0 and 100.
S-103	Reason code of XXX requires that the score be 0.
S-104	The PT Score Submission Date cannot be greater than the test year (CCYY) plus one.
S-105	The PT Score Submission Date must be equal to the test year (CCYY).
S-106	No enrollment record found for Lab ##D#####, PT Program ###, Analyte ### and Test Year CCYY.
S-107	The non-routine score has a PT Score Submission Date CCYMMDD that matches an enrollment record.
S-108	Warning: No score record found to correct, system will add a score record for this lab.
S-109	No score record found to delete.
S-110	Score record already exists, no action taken.
S-111	Warning: The score information for this lab has already been reported by another PT Program.
S-112	Score submission date does not match the corresponding score submission date on the enrollment record.
S-113	Reason Code <reason code> is not valid.

## Analytes

<b>Group ID</b>	<b>Analyte ID</b>	<b>Description</b>	<b>Minimum Passing Score</b>
N/A	0005	Bacteriology	80
N/A	0015	Mycobacteriology	80
N/A	0025	Mycology	80
N/A	0035	Parasitology	80
N/A	0045	Virology	80

<b>Group ID</b>	<b>Analyte ID</b>	<b>Description</b>	<b>Minimum Passing Score</b>
N/A	0055	Syphilis Serology	80
0065		General Immunology	80
0065	0075	Alpha-1 Antitrypsin	80
0065	0085	Alpha-Fetoprotein (tumor marker)	80
0065	0095	Antinuclear Antibody	80
0065	0105	Antistreptolysin O	80
0065	0115	Anti-Human Immunodeficiency Virus (HIV)	80
0065	0125	Complement C3	80
0065	0135	Complement C4	80
0065	0145	Hepatitis marker (HBs Ag)	80
0065	0155	Hepatitis marker (Anti-HBc)	80
0065	0165	Hepatitis marker (HBeAg)	80
0065	0175	Ig A	80
0065	0185	Ig G	80
0065	0195	Ig E	80
0065	0205	Ig M	80
0065	0215	Infectious Mononucleosis	80
0065	0225	Rheumatoid Factor	80
0065	0235	Rubella	80
0245		Routine Chemistry	80
0245	0255	Alanine Aminotransferase	80
0245	0265	Albumin	80
0245	0275	Alkaline Phosphatase	80
0245	0285	Amylase	80
0245	0295	Aspartate Aminotransferase	80
0245	0305	Bilirubin, Total	80
0245	0315	Blood Gas (pH)	80
0245	0325	Blood Gas (pO2)	80
0245	0335	Blood Gas (pCO2)	80
0245	0345	Calcium, Total	80
0245	0355	Chloride	80
0245	0365	Cholesterol, Total	80
0245	0375	Cholesterol, High Density Lipoprotein	80
0245	0385	Creatine Kinase, Total	80
0245	0395	Creatine Kinase, Isoenzyme	80
0245	0405	Creatinine	80
0245	0415	Glucose (excluding measurements on device cleared by FDA for home use)	80
0245	0425	Iron, Total	80

<b>Group ID</b>	<b>Analyte ID</b>	<b>Description</b>	<b>Minimum Passing Score</b>
0245	0435	Lactate Dehydrogenase (LDH)	80
0245	0445	LDH Isoenzyme	80
0245	0455	Magnesium	80
0245	0465	Potassium	80
0245	0475	Sodium	80
0245	0485	Total Protein	80
0245	0495	Triglycerides	80
0245	0505	Urea Nitrogen	80
0245	0515	Uric Acid	80
0525		Endocrinology	80
0525	0535	Cortisol	80
0525	0545	Free Thyroxine	80
0525	0555	Human Chorionic Gonadotropin	80
0525	0565	T3 Uptake	80
0525	0575	Triiodothyronine	80
0525	0585	Thyroid Stimulating Hormone	80
0525	0595	Thyroxine	80
0605		Toxicology	80
0605	0615	Alcohol (Blood)	80
0605	0625	Blood Lead	80
0605	0635	Carbamazepine	80
0605	0645	Digoxin	80
0605	0655	Ethosuximide	80
0605	0665	Gentamicin	80
0605	0675	Lithium	80
0605	0685	Phenobarbital	80
0605	0695	Phenytoin	80
0605	0705	Primidone	80
0605	0715	Procainamide (and Metabolite)	80
0605	0725	Quinidine	80
0605	0735	Theophylline	80
0605	0745	Tobramycin	80
0605	0755	Valproic Acid	80
0760		Hematology	80
0760	0765	Cell Ident. Or White Blood Cell Differential	80
0760	0775	Erythrocyte Count	80
0760	0785	Hematocrit (excluding Spun Microhematocrit)	80
0760	0795	Hemoglobin	80
0760	0805	Leukocyte Count	80

---

<b>Group ID</b>	<b>Analyte ID</b>	<b>Description</b>	<b>Minimum Passing Score</b>
0760	0815	Platelet Count	80
0760	0825	Fibrinogen	80
0760	0835	Partial Thromboplastin Time	80
0760	0845	Prothrombin Time	80
N/A	0855	Unexpected Antibody Detection	80
0860		ABO/RHO	100
0860	0865	ABO Group	100
0860	0875	D (RHO) Typing	100
N/A	0885	Antibody Identification	80
N/A	0895	Compatibility Testing	100

## Help Desk

The Help Desk can assist you with any issue you have related to CLIA Proficiency Testing specifications, or issues you may encounter in production.

**Call:** 888-477-7876

**Email:** [help@qtso.com](mailto:help@qtso.com)

**Hours:** 6AM to 6PM MST (leave a message off hours)



# PT Upload

The PT Upload application features are available as part of the ASPEN Web CLIA Maintenance system. You can use PT Upload to:

- Upload PT testing results to CMS’s national database
- View a list of uploaded PT files
- Review individual uploaded PT files
- View the Error and Statistics files generated when the PT files are processed

## Accessing PT Upload

### To open PT Upload:

- 1 Log into **ASPEN Web**.

Upon successful login to ASPEN Web, the **Select Application** page is presented.

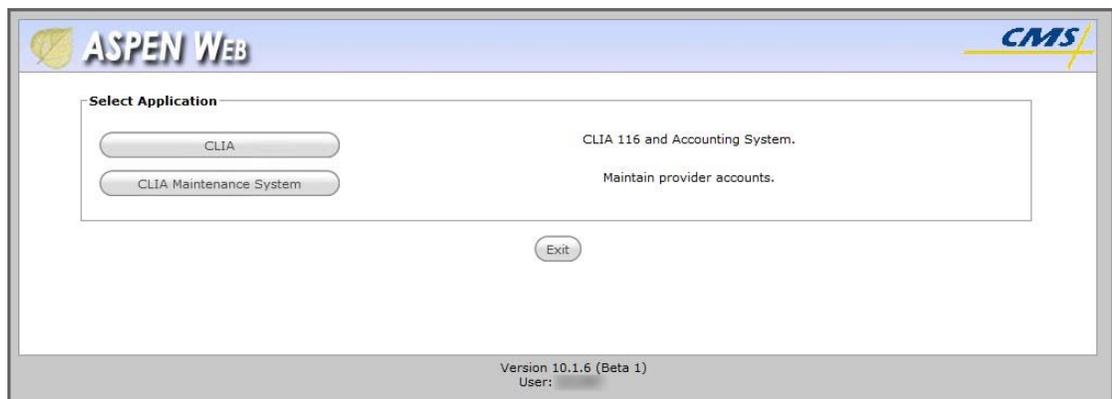


Figure 2: ASPEN Web Select Application page

- 2 Select the **CLIA Maintenance System** option to open the **CLIA Maintenance Select Application** page.

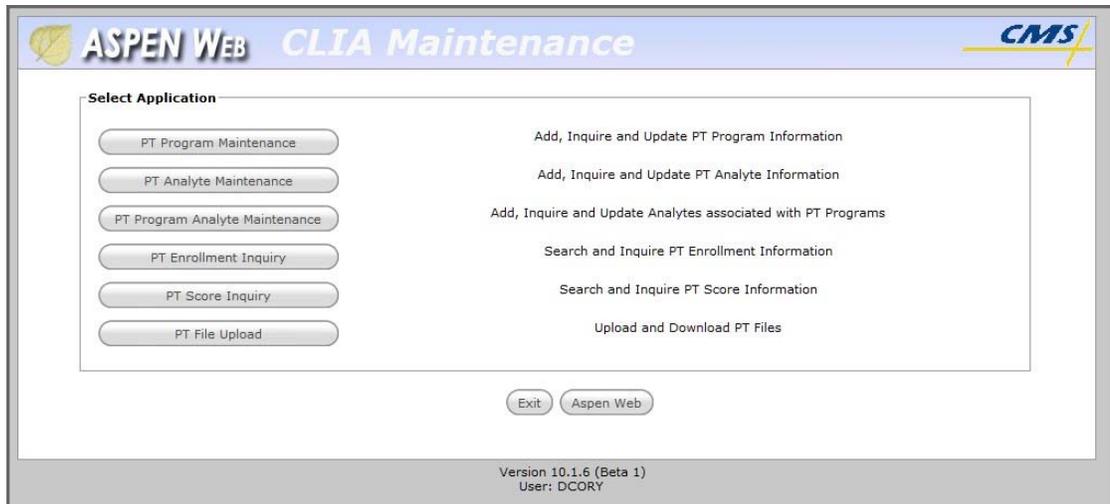


Figure 3: CLIA Maintenance Select Application page

- 3 Select the **PT File Upload** option to open the **PT Upload** page.

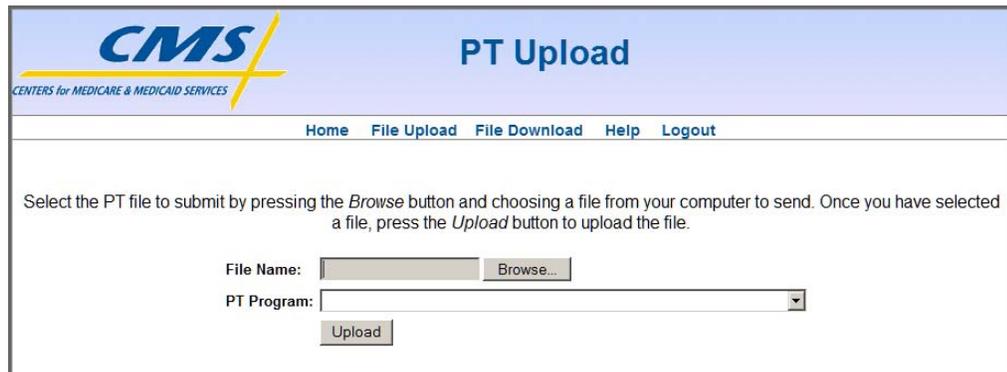


Figure 4: PT Upload page

## PT Upload Navigation

Each page of the PT Upload system includes a menu bar that provides access to the features of the PT Upload system.



Figure 5: PT Upload menu bar

The PT Upload menu bar offers the following links:

Link Name	Action
Home	Returns to the CLIA Maintenance Select Application page.
File Upload	Opens the PT Upload - File Upload page to upload a PT file.
File Download	Opens the PT Upload - File Download page to download report files.
Help	Opens the PT Upload - Help page.
Logout	Logs user out of ASPEN Web.

If you wish to navigate the PT Upload system without a mouse, the following keyboard shortcut keys are available to bring focus to items on the PT Upload system menu bar:

Shortcut Key	To Access
Alt + 1	CLIA Maintenance Select Application page (Home)
Alt + u	File Upload page
Alt + x	File Download page
Alt + p	Help page
Alt + o	Logout

With focus on an item, press the Enter key to access the associated page or activate the function.

When utilizing the keyboard to navigate the system, use **Alt + n** if you wish to bypass the PT Upload system menu bar and go directly to the first field on a page.

**Note:** Shortcut keys utilizing numbers function only with the numeric keys along the top of the keyboard. They do not function with the keys on the 10-key number pad of the keyboard.

## File Upload

The PT Upload – File Upload page is presented when you initially access the PT Upload system.

Figure 6: PT Upload - File Upload page

The File Upload page includes the following elements:

- Instructions: “Select the PT file ...”
- File Name, read-only text field
- Browse... button
- PT Program, drop-down list (optional)
  - This field is displayed only for those users with access to multiple PT Programs.
- Upload button

The following keyboard shortcut keys are available to bring focus to items on the PT Upload - File Upload page:

Shortcut Key	To Access
Alt + 2	File Name field
Alt + 3	PT Program list

**Note:** Shortcut keys utilizing numbers function only with the numeric keys along the top of the keyboard. They do not function with the keys on the 10-key number pad of the keyboard.

### To upload a PT file:

- 1 Open the **PT Upload - File Upload** page.

It opens by default when you access PT Upload.

From another page within PT Upload, select the **File Upload** option from the menu bar.

- 2 Select the **Browse** button.

A Windows **Choose File to Upload** (or similar) dialog box opens.

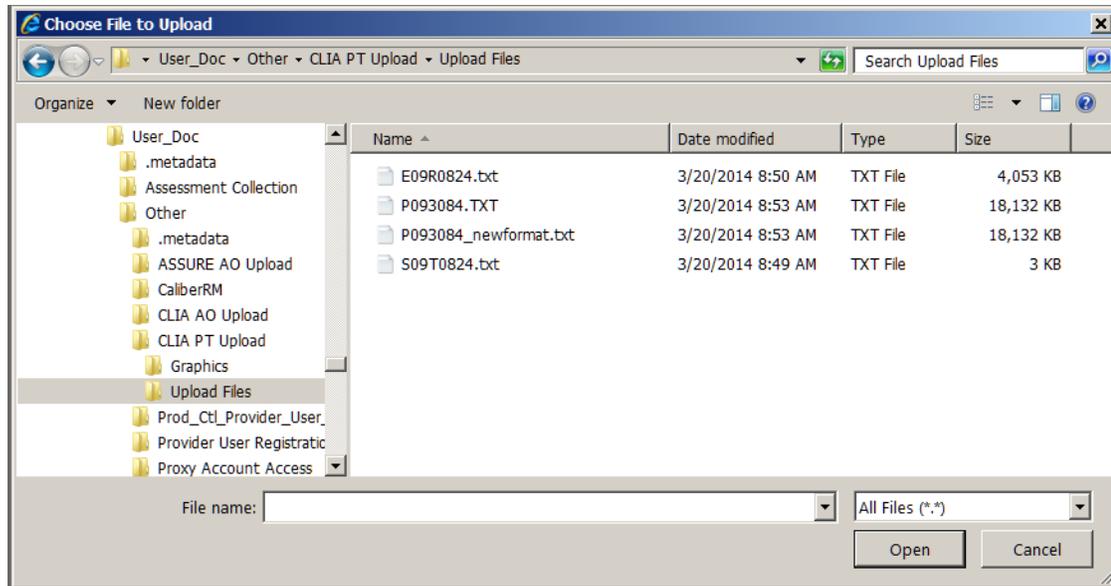


Figure 7: Choose File to Upload dialog box

**Note:** You can only upload text (.txt) files with the PT Upload function.

- 3 Navigate to the folder in which the PT file you wish to upload is located.
- 4 Select (highlight) the file name and select the **Open** button.

The path and name of the PT file you selected now appears in the File Name field on the PT Upload - File Upload page.

**Note:** The name of a PT file is limited to 35 characters.

Figure 8: PT Upload - File Upload Page with file selected

- 5 If applicable, select the appropriate **PT Program**.

6 Select the **Upload** button.

If you attempt to upload a PT file with the batch date of a file that has already been uploaded but not processed, you will receive a message.

The screenshot shows the CMS PT Upload page. At the top left is the CMS logo with the text 'CENTERS for MEDICARE & MEDICAID SERVICES'. To the right is the title 'PT Upload'. Below the logo is a navigation bar with links: Home, File Upload, File Download, Help, and Logout. The main content area contains a message box with the text: 'Processing this file will overwrite another file previously submitted. Please confirm to continue the file processing or cancel to stop the upload process.' Below this message is a question: 'Do you want to overwrite the existing file with the same batch date?' and two buttons: 'Overwrite' and 'Cancel'.

Figure 9: File already uploaded message

7 Select the **Overwrite** button to proceed with the upload, or the **Cancel** button to terminate the upload request.

While the PT file is uploading, the system displays a notification.

The screenshot shows the CMS PT Upload page. At the top left is the CMS logo with the text 'CENTERS for MEDICARE & MEDICAID SERVICES'. To the right is the title 'PT Upload'. Below the logo is a navigation bar with links: Home, File Upload, File Download, Help, and Logout. The main content area contains a message box with the text: 'Upload in progress ...'. Below this message is a text box with the text: 'Select the PT file to submit by pressing the Browse button and choosing a file from your computer to send. Once you have selected a file, press the Upload button to upload the file.' Below this text are two input fields: 'File Name: V:\QIES\_Prod\_Coord\U Browse...' and 'PT Program: 009 - COLLEGE OF AMER PATHOLOGISTS/EXCEL'. Below these fields is an 'Upload' button.

Figure 10: Upload in progress message

The system informs you when the upload is successfully completed.

The screenshot shows the CMS PT Upload page. At the top left is the CMS logo with the text 'CENTERS for MEDICARE & MEDICAID SERVICES'. To the right is the title 'PT Upload'. Below the logo is a navigation bar with links: Home, File Upload, File Download, Help, and Logout. The main content area contains a message box with the text: 'File upload has been successfully completed.'

Figure 11: Successful upload message

**Note:** Uploaded PT files are processed on a weekly basis and delivered to CDC, whether successfully processed or not.

## File Download

The PT Upload application includes functionality accessed through the File Download page to:

- View a list of uploaded PT files
- Review individual uploaded PT files
- Download Error and Statistics files created when uploaded PT files are processed.

Submission Date	File Name	PT Program	Batch Date	Status	Submission File Download	Statistics File Download	Error File Download	Recall File
2014-03-26 10:15:19	PT33_20140326	033 - DEB PT 033	2014-03-26	File Validation Succeeded	Download	Download	Download	Recall File
2014-03-24 16:19:10	PT30_working	033 - DEB PT 033	2014-03-21	File Processed	Download	Download	Download	Recall File
2014-03-24 16:17:21	PT30_working	033 - DEB PT 033	2014-03-11	File Load Failed	Download	Download	Download	Recall File

Figure 12: PT Upload - File Download page

The File Download page displays, in tabular format, one record (row) for each uploaded PT file. By default, the File Download page lists the PT files that were uploaded in the last seven days in descending Submission Date order (most recent first).

The table displaying the uploaded files has the following column headings:

- Submission Date – date and time the file was uploaded
- File Name – name of the uploaded file
- PT Program – PT Program Code and Name
- Batch Date – batch date in header of the uploaded PT file
- Status – processing status of the uploaded PT file:
  - File Load Failed – Errors were encountered in the uploaded PT file that prevented a successful upload. An Error file identifying the error(s) is available for download.
  - File Validation Succeeded – No initial validation errors were detected by the upload process. The PT file was uploaded successfully and is ready to be processed. You can recall the file if necessary.

- File Validation Failed – Initial validation errors were encountered by the upload process. An Error file identifying the error(s) is available for download.
- File Processed – The CLIA PT system processed the uploaded PT file. A Statistics file and, if errors were encountered, an Error file may be available for download.
- File Recalled – The uploaded file was recalled. The CLIA PT system will not process this file.
- Submission File Download – contains a Download button you can use to download and review the associated uploaded PT file.
- Statistics File Download – contains a Download button you can use to download and view the Statistics file associated with the uploaded PT file. The Statistics file is available only after the uploaded PT file is processed by the CLIA PT system.
- Error File Download – contains a Download button you can use to download and view, if available, the Error file associated with the uploaded PT file. The Error file may detail upload errors or processing errors.
- Recall File – contains a Recall button you can use to recall the associated uploaded PT file if it has not yet been processed by the CLIA PT system.

The File Download page includes the following elements you can use to specify alternate criteria for selecting the uploaded PT files to list:

- To Date (mm/dd/yyyy), text field
- Prior Days, drop-down list  
Options are 0, 1, 2, 5,10, and 30.
- Refresh button

The To Date field value defaults to the current date and the Prior Days field value initially defaults to 7. With these criteria, the file(s) you uploaded today and for the last 7 days display.

**To change PT file listing criteria:**

- 1 Change the **To Date** and/or the **Prior Days** field values to limit or expand the list.
- 2 Select the **Refresh** button to perform the new query and update the list of uploaded PT files.

## Example

To view a list of uploaded files for yesterday and today, leave the current date in the To Date field and change the Prior Days field value to 1. If the Prior Days field value is 0, only PT files uploaded today display.

The following keyboard shortcut keys are available to bring focus to items on the PT Upload - File Download page:

Shortcut Key	To Access
Alt + 2	To Date field
Alt + 3	Prior Days list
Alt + s	Refresh button

**Note:** Shortcut keys utilizing numbers function only with the numeric keys along the top of the keyboard. They do not function with the keys on the 10-key number pad of the keyboard.

### To view an uploaded PT file, or an associated Statistics or Error file:

- 1 On the **PT Upload** menu bar, select the **File Download** option to open the **PT Upload - File Download** page.
- 2 To open an uploaded PT file, a Statistics file, or an Error file, select the **Download** button in (respectively) the **Submission File Download**, **Statistics File Download**, or **Error File Download** column for the PT file of interest.

A **File Download** dialog box opens. In the example shown below, a Statistics file was selected for download.

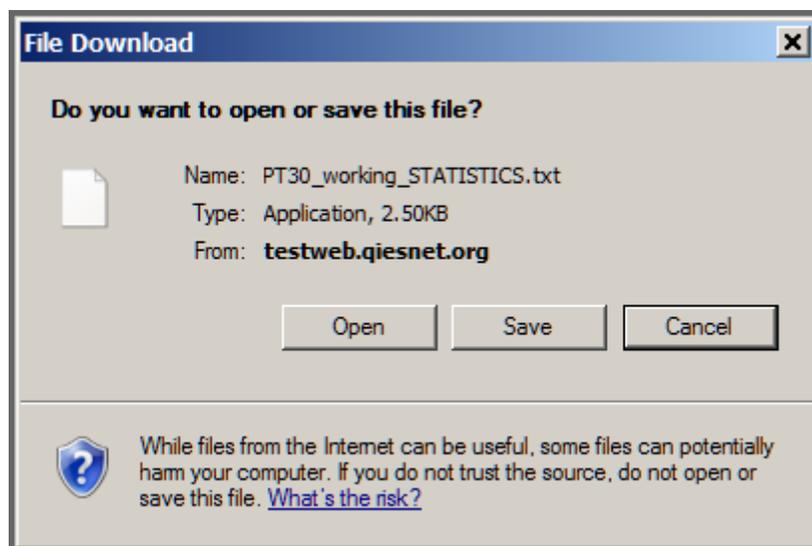


Figure 13: File Download dialog box

### 3 Select the **Open** button.

The file (a Statistics file in this case) opens in your computer's default text editor.

```

PGM = 033, FILE = PT30_working
TOTAL PROFICIENCY TESTING RECORDS IN THIS UPDATE = 0000001
TOTAL ERROR MESSAGES GENERATED FOR THIS UPDATE = 0000007
TOTAL WARNING MESSAGES GENERATED FOR THIS UPDATE = 0000000
TOTAL ENROLLMENT TRANSACTIONS PROCESSED = 0000001
TOTAL ENROLLMENT RECORDS ADDED = 0000000
TOTAL ENROLLMENT RECORDS CORRECTED = 0000000
TOTAL ENROLLMENT RECORDS DELETED = 0000000
TOTAL ENROLLMENT TRANSACTIONS REJECTED = 0000001
TOTAL SCORE TRANSACTIONS PROCESSED = 0000000
TOTAL SCORE RECORDS ADDED = 0000000
TOTAL SCORE RECORDS CORRECTED = 0000000
TOTAL SCORE RECORDS DELETED = 0000000
TOTAL SCORE TRANSACTIONS REJECTED = 0000000

PT MISSING SCORES FOR TEST YEAR 2012 SECOND EVENT COMPARE
  SCORE WITH NO MATCHING ENROLLMENT (Informational)
  ENROLLMENT WITH BLANK SCORE SUBMISSION DATE (Warning)
  ENROLLMENT WITH NO SCORE (Error)
ORG = 033 ENRL = 00000000 MATCH = 00000000 NO MATCH = 00000000 = 0.00%

PT MISSING SCORES FOR TEST YEAR 2012 THIRD EVENT COMPARE
  SCORE WITH NO MATCHING ENROLLMENT (Informational)
  ENROLLMENT WITH BLANK SCORE SUBMISSION DATE (Warning)
  ENROLLMENT WITH NO SCORE (Error)
ORG = 033 ENRL = 00000000 MATCH = 00000000 NO MATCH = 00000000 = 0.00%

PT MISSING SCORES FOR TEST YEAR 2013 FIRST EVENT COMPARE
  SCORE WITH NO MATCHING ENROLLMENT (Informational)
  ENROLLMENT WITH BLANK SCORE SUBMISSION DATE (Warning)
  ENROLLMENT WITH NO SCORE (Error)
ORG = 033 ENRL = 00000000 MATCH = 00000000 NO MATCH = 00000000 = 0.00%

PT MISSING SCORES FOR TEST YEAR 2013 SECOND EVENT COMPARE
  SCORE WITH NO MATCHING ENROLLMENT (Informational)
  ENROLLMENT WITH BLANK SCORE SUBMISSION DATE (Warning)
  ENROLLMENT WITH NO SCORE (Error)
ORG = 033 ENRL = 00000000 MATCH = 00000000 NO MATCH = 00000000 = 0.00%

PT MISSING SCORES FOR TEST YEAR 2013 THIRD EVENT COMPARE
  SCORE WITH NO MATCHING ENROLLMENT (Informational)
  ENROLLMENT WITH BLANK SCORE SUBMISSION DATE (Warning)
  ENROLLMENT WITH NO SCORE (Error)
ORG = 033 ENRL = 00000000 MATCH = 00000000 NO MATCH = 00000000 = 0.00%

PT MISSING SCORES FOR TEST YEAR 2014 FIRST EVENT COMPARE
  SCORE WITH NO MATCHING ENROLLMENT (Informational)
  ENROLLMENT WITH BLANK SCORE SUBMISSION DATE (Warning)
  ENROLLMENT WITH NO SCORE (Error)
ORG = 033 ENRL = 00000000 MATCH = 00000000 NO MATCH = 00000000 = 0.00%

```

Figure 14: Example Statistics file

### 4 If desired, save the file to your computer.

## Help

The PT Upload - Help page provides links to the following items:

- Accessibility Policy
- Contact Us
- Privacy Policy



Figure 15: PT Upload - Help page

The following keyboard shortcut keys are available to bring focus to the links on the PT Upload- Help page:

Shortcut Key	To Access
Alt + 7	Accessibility Policy link
Alt + 8	Contact Us link
Alt + 9	Privacy Policy link

With focus on one of these links, press the Enter key to activate the link and access the associated page.

**Note:** Shortcut keys utilizing numbers function only with the numeric keys along the top of the keyboard. They do not function with the keys on the 10-key number pad of the keyboard.

## Accessibility Policy

The PT Upload - Accessibility Policy page outlines the PT Upload system's accessibility policy in regards to compliance with Section 508 of the U.S. Rehabilitation Act and the W3C's Web Content Accessibility Guidelines.

**CMS**  
CENTERS for MEDICARE & MEDICAID SERVICES

**PT Upload**

[Home](#) [File Upload](#) [File Download](#) [Help](#) [Logout](#)

[Accessibility Policy](#) | [Contact Us](#) | [Privacy Policy](#)

### Accessibility Policy

The QIES Technical Support Office makes every effort to ensure our Web site is accessible for people with disabilities and meets current accessibility standards, including those defined by Section 508 of the U.S. Rehabilitation Act and the W3C's Web Content Accessibility Guidelines. We are actively engaged in the ongoing process of testing our Web site for compliance with current accessibility standards.

We are committed to addressing issues that prevent people with disabilities from accessing our site and its content in a timely manner. If you should find that you are unable to or have difficulty accessing information via our Web site, please contact our help desk.

E-mail: [help@qtso.com](mailto:help@qtso.com)  
Phone: 800-339-9313

Figure 16: PT Upload - Accessibility Policy page

## Contact Us

The PT Upload - Contact Us page provides e-mail and telephone contact information for the QIES Technical Support Office (QTSO) Help Desk.

**CMS**  
CENTERS for MEDICARE & MEDICAID SERVICES

**PT Upload**

[Home](#) [File Upload](#) [File Download](#) [Help](#) [Logout](#)

[Accessibility Policy](#) | [Contact Us](#) | [Privacy Policy](#)

### Contact Us

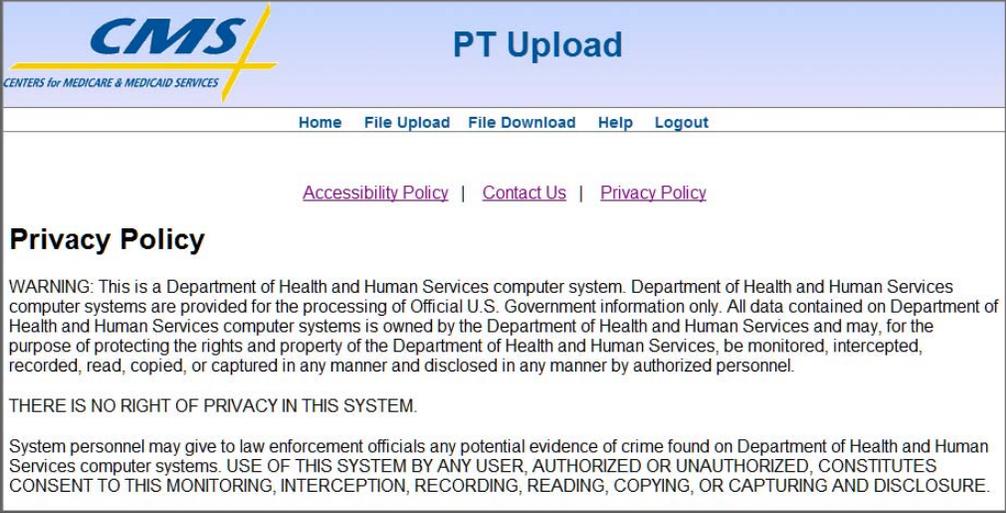
If you should find that you are unable to or have difficulty accessing information via this Web site, please contact the help desk.

QTSO Help Desk  
E-Mail: [help@qtso.com](mailto:help@qtso.com)  
Phone: 800-339-9313  
Fax: 888-477-7871

Figure 17: PT Upload - Contact Us page

## Privacy Policy

The PT Upload - Privacy Policy page outlines the PT Upload system's privacy policy.



**CMS**  
CENTERS for MEDICARE & MEDICAID SERVICES

## PT Upload

[Home](#) [File Upload](#) [File Download](#) [Help](#) [Logout](#)

[Accessibility Policy](#) | [Contact Us](#) | [Privacy Policy](#)

### Privacy Policy

WARNING: This is a Department of Health and Human Services computer system. Department of Health and Human Services computer systems are provided for the processing of Official U.S. Government information only. All data contained on Department of Health and Human Services computer systems is owned by the Department of Health and Human Services and may, for the purpose of protecting the rights and property of the Department of Health and Human Services, be monitored, intercepted, recorded, read, copied, or captured in any manner and disclosed in any manner by authorized personnel.

THERE IS NO RIGHT OF PRIVACY IN THIS SYSTEM.

System personnel may give to law enforcement officials any potential evidence of crime found on Department of Health and Human Services computer systems. USE OF THIS SYSTEM BY ANY USER, AUTHORIZED OR UNAUTHORIZED, CONSTITUTES CONSENT TO THIS MONITORING, INTERCEPTION, RECORDING, READING, COPYING, OR CAPTURING AND DISCLOSURE.

Figure 18: PT Upload - Privacy Policy page



# Terminology

**Term:** Automated Survey Processing Environment

**Acronym:** ASPEN

**Description:** ASPEN provides state-level secure data collection of healthcare provider demographic, surveillance and certification information, with timely replication of required information into the national repository.

**Term:** Clinical Laboratory Improvement Amendments

**Acronym:** CLIA

**Description:** Legislation establishing quality standards for laboratory testing.

**Term:** Center for Medicare and Medicaid Services

**Acronym:** CMS

**Description:** CMS provides direction and technical guidance for the administration of the Federal effort to plan, develop, manage and evaluate health care financing programs and policies.

**Term:** Central Office

**Acronym:** CO

**Description:** CMS Central Office.

**Term:** Proficiency Testing

**Acronym:** PT

**Description:** The testing of unknown samples sent to a laboratory by a CMS-approved PT Program. Most sets of PT samples are sent to participating laboratories three times per year. After testing the PT samples in the same manner as its patient specimens, the laboratory reports its sample results back to its PT Program. The Program grades the results using the CLIA grading criteria and sends the laboratory scores reflecting how accurately it performed the testing.

