

# CRF Report for Study E7694105S

Report run by Tressa Brown at 11-FEB-2013 10:52:17

## Report Parameters

Site: CDB\_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R1017

Ending patient: R1017

### Legend: How different values appear in the report

Prompt	Abc 123
Data value	Abc 123
Data value with discrepancy	<b>Abc 123</b>

All time stamps displayed in this report are in the timezone of the database server.

The data contained in this report is current at the time of printing (time as shown above)



Initials:

(b)

Subject #:

R1017

BASELINE

Is Blank

MINNESOTA NICOTINE WITHDRAWAL SCALE

Minnesota Nicotine Withdrawal Scale (check answers)

Time Taken:  (24-hr clock)

Please rate yourself for the period of the last 24 hours.  
0 = none, 1 = slight, 2 = mild, 3 = moderate, 4 = severe

- |   |                                     |                          |                                     |                          |                          |                          |                                     |                                     |                          |
|---|-------------------------------------|--------------------------|-------------------------------------|--------------------------|--------------------------|--------------------------|-------------------------------------|-------------------------------------|--------------------------|
| 1. Angry, irritable, frustrated                 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/> |
| 2. Anxious, nervous                             | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/> |
| 3. Depressed mood, sad                          | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/> |
| 4. Desire or craving to smoke                   | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 5. Difficulty concentrating                     | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/> |
| 6. Increased appetite, hungry, weight gain      | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> |
| 7. Insomnia, sleep problems, awakening at night | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/> |
| 8. Restless                                     | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/> |
| 9. Impatient                                    | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/> |

Date:

Total Score:

Verified  Approved  Locked  Frozen

Page Version No. WITHDRAWAL (v1, 25-MAR-2009)

Document Number

Initials:

(b)

Subject #:

R1017

Is Blank

FAGERSTROM TEST FOR NICOTINE DEPENDENCE

Fagerstrom Test for Nicotine Dependence (check answers)

Time Taken:  (24-hr clock)

1. How soon after waking do you smoke your first cigarette?

- Less than five minutes
- 5-30 minutes
- 31-60 minutes
- More than an hour

2. Do you find it difficult to refrain from smoking in places where it is forbidden?

- Yes
- No

3. Which cigarette would you hate to give up?

- First one in the morning?
- Any other

4. How many cigarettes do you smoke per day?

- More than 30 per day
- 21-30 per day
- 11-20 per day
- 10 or less per day

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

- Yes
- No

6. Do you smoke if you are so ill that you are in bed most of the day?

- Yes
- No

Date:

Total Score:

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Page Version No. FAGERSTROM (v1, 25-MAR-2009)

Document Number

Initials:

Subject #:

Is Blank

MINNESOTA NICOTINE WITHDRAWAL SCALE

Minnesota Nicotine Withdrawal Scale (check answers)

Time Taken:  (24-hr clock)

Please rate yourself for the period of the last 24 hours.  
0 = none, 1 = slight, 2 = mild, 3 = moderate, 4 = severe

- |   |                                       |                                       |                                       |                                       |                            |
|---|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|----------------------------|
| 1. Angry, irritable, frustrated                 | <input type="checkbox"/> 0            | <input type="checkbox"/> 1            | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 2. Anxious, nervous                             | <input checked="" type="checkbox"/> 0 | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 3. Depressed mood, sad                          | <input checked="" type="checkbox"/> 0 | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 4. Desire or craving to smoke                   | <input type="checkbox"/> 0            | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input checked="" type="checkbox"/> 3 | <input type="checkbox"/> 4 |
| 5. Difficulty concentrating                     | <input checked="" type="checkbox"/> 0 | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 6. Increased appetite, hungry, weight gain      | <input type="checkbox"/> 0            | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 7. Insomnia, sleep problems, awakening at night | <input checked="" type="checkbox"/> 0 | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 8. Restless                                     | <input type="checkbox"/> 0            | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 9. Impatient                                    | <input type="checkbox"/> 0            | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |

Date:

Total Score:

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Page Version No. WITHDRAWAL (v1, 25-MAR-2009)

Document Number

Initials:

(b)

Subject #:

R1017

WEEK 10

Is Blank

MINNESOTA NICOTINE WITHDRAWAL SCALE

Minnesota Nicotine Withdrawal Scale (check answers)

Time Taken:  (24-hr clock)

Please rate yourself for the period of the last 24 hours.  
0 = none, 1 = slight, 2 = mild, 3 = moderate, 4 = severe

- |   |                                       |                                       |                            |                                       |                            |
|---|---------------------------------------|---------------------------------------|----------------------------|---------------------------------------|----------------------------|
| 1. Angry, irritable, frustrated                 | <input type="checkbox"/> 0            | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 2. Anxious, nervous                             | <input type="checkbox"/> 0            | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 3. Depressed mood, sad                          | <input type="checkbox"/> 0            | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 4. Desire or craving to smoke                   | <input type="checkbox"/> 0            | <input type="checkbox"/> 1            | <input type="checkbox"/> 2 | <input checked="" type="checkbox"/> 3 | <input type="checkbox"/> 4 |
| 5. Difficulty concentrating                     | <input checked="" type="checkbox"/> 0 | <input type="checkbox"/> 1            | <input type="checkbox"/> 2 | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 6. Increased appetite, hungry, weight gain      | <input type="checkbox"/> 0            | <input type="checkbox"/> 1            | <input type="checkbox"/> 2 | <input checked="" type="checkbox"/> 3 | <input type="checkbox"/> 4 |
| 7. Insomnia, sleep problems, awakening at night | <input checked="" type="checkbox"/> 0 | <input type="checkbox"/> 1            | <input type="checkbox"/> 2 | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 8. Restless                                     | <input type="checkbox"/> 0            | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 9. Impatient                                    | <input type="checkbox"/> 0            | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |

Date:

Total Score:

Verified  Approved  Locked  Frozen

Page Version No. WITHDRAWAL (v1, 25-MAR-2009)

Document Number

Initials:

(b)

Subject #:

R1017

WEEK 16

Is Blank

MINNESOTA NICOTINE WITHDRAWAL SCALE

Minnesota Nicotine Withdrawal Scale (check answers)

Time Taken:  (24-hr clock)

Please rate yourself for the period of the last 24 hours.  
0 = none, 1 = slight, 2 = mild, 3 = moderate, 4 = severe

- |   |                                       |                            |                                       |                                       |                                       |
|---|---------------------------------------|----------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| 1. Angry, irritable, frustrated                 | <input type="checkbox"/> 0            | <input type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input checked="" type="checkbox"/> 3 | <input type="checkbox"/> 4            |
| 2. Anxious, nervous                             | <input type="checkbox"/> 0            | <input type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input checked="" type="checkbox"/> 3 | <input type="checkbox"/> 4            |
| 3. Depressed mood, sad                          | <input type="checkbox"/> 0            | <input type="checkbox"/> 1 | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 3            | <input type="checkbox"/> 4            |
| 4. Desire or craving to smoke                   | <input type="checkbox"/> 0            | <input type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input checked="" type="checkbox"/> 4 |
| 5. Difficulty concentrating                     | <input type="checkbox"/> 0            | <input type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input checked="" type="checkbox"/> 3 | <input type="checkbox"/> 4            |
| 6. Increased appetite, hungry, weight gain      | <input type="checkbox"/> 0            | <input type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input checked="" type="checkbox"/> 3 | <input type="checkbox"/> 4            |
| 7. Insomnia, sleep problems, awakening at night | <input checked="" type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4            |
| 8. Restless                                     | <input type="checkbox"/> 0            | <input type="checkbox"/> 1 | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 3            | <input type="checkbox"/> 4            |
| 9. Impatient                                    | <input type="checkbox"/> 0            | <input type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input checked="" type="checkbox"/> 3 | <input type="checkbox"/> 4            |

Date:

Total Score:

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Page Version No. WITHDRAWAL (v1, 25-MAR-2009)

Document Number

## **Links to Discrepancy and Audit Sections**

[Click here to navigate to audit history for this CRF](#)

[Click here to navigate to discrepancy details for this CRF](#)

Initials:

(b)

Subject #:

R1017

WEEK 16

Is Blank

Did subject smoke at least 1 cigarette per day during the past week?  Yes  No

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Page Version No. FAG-INDICA (v1, 30-DEC-2009)

Document Number R289382613

Initials:

(b)

Subject #:

R1017

WEEK 16

Is Blank

FAGERSTROM TEST FOR NICOTINE DEPENDENCE

Fagerstrom Test for Nicotine Dependence (check answers)

Time Taken:  (24-hr clock)

1. How soon after waking do you smoke your first cigarette?

- Less than five minutes
- 5-30 minutes
- 31-60 minutes
- More than an hour

2. Do you find it difficult to refrain from smoking in places where it is forbidden?

- Yes
- No

3. Which cigarette would you hate to give up?

- First one in the morning?
- Any other

4. How many cigarettes do you smoke per day?

- More than 30 per day
- 21-30 per day
- 11-20 per day
- 10 or less per day

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

- Yes
- No

6. Do you smoke if you are so ill that you are in bed most of the day?

- Yes
- No

Date:

Total Score:

Verified  Approved  Locked  Frozen

Page Version No. FAGERSTROM (v1, 25-MAR-2009)

Document Number

Initials:

(b)

Subject #:

R1017

WEEK 28

Is Blank

MINNESOTA NICOTINE WITHDRAWAL SCALE

Minnesota Nicotine Withdrawal Scale (check answers)

Time Taken:  (24-hr clock)

Please rate yourself for the period of the last 24 hours.  
0 = none, 1 = slight, 2 = mild, 3 = moderate, 4 = severe

- |   |                                       |                                       |                                       |                                       |                            |
|---|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|----------------------------|
| 1. Angry, irritable, frustrated                 | <input type="checkbox"/> 0            | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 2. Anxious, nervous                             | <input checked="" type="checkbox"/> 0 | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 3. Depressed mood, sad                          | <input type="checkbox"/> 0            | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 4. Desire or craving to smoke                   | <input type="checkbox"/> 0            | <input type="checkbox"/> 1            | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 5. Difficulty concentrating                     | <input checked="" type="checkbox"/> 0 | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 6. Increased appetite, hungry, weight gain      | <input type="checkbox"/> 0            | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input checked="" type="checkbox"/> 3 | <input type="checkbox"/> 4 |
| 7. Insomnia, sleep problems, awakening at night | <input checked="" type="checkbox"/> 0 | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 8. Restless                                     | <input checked="" type="checkbox"/> 0 | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 9. Impatient                                    | <input type="checkbox"/> 0            | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |

Date:

Total Score:

Verified  Approved  Locked  Frozen

Page Version No. WITHDRAWAL (v1, 25-MAR-2009)

Document Number

Initials:

(b)

Subject #:

R1017

WEEK 28

Is Blank

Did subject smoke at least 1 cigarette per day during the past week?  Yes  No

Verified  Approved  Locked  Frozen

Page Version No. FAG-INDICA (v1, 30-DEC-2009)

Document Number R289382813

Initials:

(b)

Subject #:

R1017

WEEK 28

Is Blank

FAGERSTROM TEST FOR NICOTINE DEPENDENCE

Fagerstrom Test for Nicotine Dependence (check answers)

Time Taken:  (24-hr clock)

1. How soon after waking do you smoke your first cigarette?

- Less than five minutes
- 5-30 minutes
- 31-60 minutes
- More than an hour

2. Do you find it difficult to refrain from smoking in places where it is forbidden?

- Yes
- No

3. Which cigarette would you hate to give up?

- First one in the morning?
- Any other

4. How many cigarettes do you smoke per day?

- More than 30 per day
- 21-30 per day
- 11-20 per day
- 10 or less per day

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

- Yes
- No

6. Do you smoke if you are so ill that you are in bed most of the day?

- Yes
- No

Date:

Total Score:

Verified  Approved  Locked  Frozen

Page Version No. FAGERSTROM (v1, 25-MAR-2009)

Document Number

## Appendix: Audit and Discrepancy Information



# Audit History Report

This section lists audited data that meets the parameters set when the report was run. It may not include all of the audited data in a particular CRF. Refer to the documentation for a complete description of the parameters that can affect this report.

**Document #:** R267248113

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1017 CDB_001	Week 16	Withdrawal Scale 05

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Withdrawal Scale	Page number	2	Week 16

<b>Group #</b>	<b>Group Name</b>
1	DRUGSCR

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on resequence</b>	<b>On By</b>	<b>Reason Comment</b>
Total Score (10) 1	NA		04-SEP-2009 14:44:49 Rossana Matos	Data Entry Error
Total Score (10) 1	NA 23		08-OCT-2009 09:34:59 Sharon Daly	Data Entry Error

# Discrepancy Detail Report

Document #: R267248113

Discrepancy ID: 1766241613                      Site: CDB\_001                      Patient: R1017  
Visit: WEEK 16                      Visit Date:  
CRF: WITHDRAWAL SCAL                      Section: WITHDRAWAL SCALE                      Qualifying Value: 2  
Field: Total Score                      Row: 1  
Value Text: 23  
Type: MANUAL                      Status: CURRENT  
Review Status: Resolved-Response Edited  
Discrepancy: Please verify should be 23.  
Internal Comment: verified  
Resolution Type: Data value changed. Disc no longer applicable.  
Resolution Text:

# Deleted CRFs Report