

CRF Report for Study E7694105S

Report run by Tressa Brown at 13-FEB-2013 11:24:06

Report Parameters

Site: L0689282_2

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R2022

Ending patient: R2022

Legend: How different values appear in the report

Prompt	Abc 123
Data value	Abc 123
Data value with discrepancy	Abc 123

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 #:

R2022

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 0 1 2 3 4
- 2. Anxious, nervous 0 1 2 3 4
- 3. Depressed mood, sad 0 1 2 3 4
- 4. Desire or craving to smoke 0 1 2 3 4
- 5. Difficulty concentrating 0 1 2 3 4
- 6. Increased appetite, hungry, weight gain 0 1 2 3 4
- 7. Insomnia, sleep problems, awakening at night 0 1 2 3 4
- 8. Restless 0 1 2 3 4
- 9. Impatient 0 1 2 3 4

Date:

Total Score:

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

Document Number

Initials:

(b)

Subject #:

R2022

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:

(b)

Subject #:

R2022

WEEK 6

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 type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 |
| 3. Depressed mood, sad | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input checked="" 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 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 type="checkbox"/> 3 | <input checked="" 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 checked="" 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 #:

R2022

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 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 type="checkbox"/> | 2 | <input checked="" 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 type="checkbox"/> | 0 | <input type="checkbox"/> | 1 | <input type="checkbox"/> | 2 | <input checked="" type="checkbox"/> | 3 | <input type="checkbox"/> | 4 |
| 8. Restless | <input type="checkbox"/> | 0 | <input type="checkbox"/> | 1 | <input type="checkbox"/> | 2 | <input checked="" 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

Initials:

(b)

Subject #:

R2022

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 type="checkbox"/> | 3 | <input type="checkbox"/> | 4 |
| 2. Anxious, nervous | <input 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 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 type="checkbox"/> | 3 | <input type="checkbox"/> | 4 |
| 5. Difficulty concentrating | <input 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 type="checkbox"/> | 3 | <input type="checkbox"/> | 4 |
| 7. Insomnia, sleep problems, awakening at night | <input 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 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 type="checkbox"/> | 3 | <input type="checkbox"/> | 4 |

Date:

Total Score:

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

Document Number R284403713

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R2022

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 R286927513

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Initials:

(b)

Subject #:

R2022

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:

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

Document Number R284403913

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R2022

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 type="checkbox"/> | 1 | <input type="checkbox"/> | 2 | <input type="checkbox"/> | 3 | <input type="checkbox"/> | 4 |
| 2. Anxious, nervous | <input 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 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 type="checkbox"/> | 3 | <input type="checkbox"/> | 4 |
| 5. Difficulty concentrating | <input 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 type="checkbox"/> | 3 | <input type="checkbox"/> | 4 |
| 7. Insomnia, sleep problems, awakening at night | <input 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 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 type="checkbox"/> | 3 | <input type="checkbox"/> | 4 |

Date:

Total Score:

Verified Approved Locked Frozen

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

Document Number R293520213

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R2022

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 R293520313

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Initials:

(b)

Subject #:

R2022

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:

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

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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 #: R284403713

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Week 16	Withdrawal Scale 05

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	17-FEB-2010 17:07:14 Amanda Lynn	Data Entry Error

Document #: R284403713

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Week 16	Withdrawal Scale 05

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Withdrawal Scale	Page number	2	Week 16

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Total Score (10) 1	10 9	14-DEC-2009 12:27:46 Amanda Lynn	Data Entry Error

Document #: R286927513

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Week 16	Fagerstrom Indicator 05.1

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
-----------------------------	--------------------------	-------------------------	----------------------

Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	17-FEB-2010 17:07:32 Amanda Lynn	Data Entry Error

Document #: R284403913

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Week 16	Fagerstrom 06

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	17-FEB-2010 17:07:37 Amanda Lynn	Data Entry Error

Document #: R293520213

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Week 28	Withdrawal Scale 07

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	17-FEB-2010 17:07:42 Amanda Lynn	Data Entry Error

Document #: R293520313

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Week 28	Fagerstrom Indicator 07.1

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	17-FEB-2010 17:07:47 Amanda Lynn	Data Entry Error

Document #: R293520413

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Week 28	Fagerstrom 08

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
-----------------------------	--------------------------	-------------------------	----------------------

Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	17-FEB-2010 17:07:52 Amanda Lynn	Data Entry Error

Discrepancy Detail Report

Deleted CRFs Report