

Participant ID

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Nickname

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Outcome visit

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Diabetes Prevention Program Outcomes Study

F06 NON-CLINIC VISIT INVENTORY

This form is completed for participants at scheduled Mid-year or Annual visits conducted outside the DPPOS clinic (01M, 01A, 02M, 02A,). Refer to the MOO for a prioritized table of procedures to collect. Clinics can complete as many sections of this form as possible. Complete Parts I-III and VII for a mid-year visit; and the entire form for an annual visit.

Complete Part II only if visit is conducted at home or at a non-clinic medical facility where necessary equipment is available.

PART I / IDENTIFICATION

A. Participant Identification

1. Clinic number [][]

2. Participant number [][][][][][][]

3. Nickname [][][][][][][]

4. Date of randomization [][][][][][][]
month day year

5. Sex Male ¹[] Female ²[]

6. Outcome visit [][][] VISIT

7. Date of visit [][][][][][][]
month day year
 KGVSTDT replaced with DAYSRAND

8. Visit Location Home ¹[]
KGVISLOC Phone ²[]
Non-clinic medical facility ³[]

KGFORMIN

Identification code of person reviewing completed form [][][] Form entered in computer? []

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PART II / PHYSICAL AND HISTORY

Complete Section B only if aneroid sphygmomanometer is available and complete Section C.1. only if balance beam scale is available for weight collection. Complete Section C2 for annual visits only.

B. Blood Pressure

1. Seated Arm Blood Pressure

a. Blood Pressure Reading 1
 (after sitting 5 minutes)

Systolic **Diastolic**
 KG SBP1 / mmHg KG DBP1

b. Blood Pressure Reading 2
 (after waiting 30 seconds)

KG SBP2 / mmHg KG DBP2

Inform participant and PCP via letter if

- The participant is **NON-DIABETIC** and if systolic BP ≥ 140 or diastolic BP ≥ 90 on the mean of 1a and 1b.
- OR
- The participant is **DIABETIC** and if systolic BP ≥ 130 or diastolic BP ≥ 80 on the mean of 1a and 1b.

C. Anthropometrics

- For C.1 – Weight, record Measure 3 only if first 2 measurements are not within 0.2 Kilograms (200g).
- For C.2 – (Annual visits only) Waist Circumference record Measure 3 only if first 2 measurements are not within 0.5 cm.

	Measure 1 KGWGHT1	Measure 2 KGWGHT2	Measure 3 KGWGHT3
1. Weight	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> kg	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> kg	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> kg
2. Waist Circumference	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> cm KGWSTC1	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> cm KGWSTC2	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> cm KGWSTC3

D. Events and Procedures

1. Since the last contact or visit, has the participant experienced any of the following?
CHECK ALL THAT APPLY

a. Any acute life threatening event?.....	<input type="checkbox"/>	KGACTT
b. Permanent or severe disability?.....	<input type="checkbox"/>	KGDISA
c. Required or prolonged hospitalization?.....	<input type="checkbox"/>	KGHOSP
d. Overdose of any medication?.....	<input type="checkbox"/>	KGOVDO
e. Pregnancy resulting in congenital abnormality or birth defect?.....	<input type="checkbox"/>	KGCONG
f. Required intervention or treatment to prevent serious adverse event?....	<input type="checkbox"/>	KGTSAE
g. Possible CVD event?.....	<input type="checkbox"/>	KGPCVD
h. Renal failure?.....	<input type="checkbox"/>	KGRENFL
i. Kidney transplant?.....	<input type="checkbox"/>	KGKIDTRNS

If checked, complete E08 for each event.

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- j. Eye procedure?..... KGRETINA 1 → Complete E09
- k. Gastric reduction surgery?..... KGGAS 1 → Complete E11

If any of options a. – i. are checked, complete a separate E08 for each event. For multiple CVD events that may occur during the same hospitalization, complete an E08 for the first CVD diagnosis and report subsequent events (from the same hospitalization) on the same E08 form.

If option j is checked, complete an E09 form. If option k is checked, complete an E11 form.

PART III/ MLS PARTICIPANT SECTION

Complete sections E and F for all MLS participants.

E. Metformin Status

1. Has the participant taken any STUDY METFORMIN since the last visit? Yes 1 No 2 KG TAKM

If YES, complete the F08 Metformin Safety & Adherence Form for this participant.

F. Dispensing of Metformin

Complete the Metformin Safety Assessment Checklist for all participants receiving study metformin before metformin is dispensed.

1. How many months of metformin was dispensed (0, 3, 6)? KG DISP

METFORMIN LABEL

Remove label from metformin before dispensing and affix here.

METFORMIN LABEL

Remove label from metformin before dispensing and affix here.

If metformin is NOT dispensed for reasons other than a previously reported permanent condition, a Metformin Discontinuation Form (Form F07) must be completed.

IF THIS IS A MID-YEAR VISIT, SKIP TO PART VII (CONCOMITANT MEDICATIONS). IF THIS IS AN ANNUAL VISIT, CONTINUE.

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Part IV/ ANNUAL ASSESSMENTS

Complete Section G for each annual visit. This section should be completed after the Neuropathy Questionnaire has been completed (Form Q15).

G. Neuropathy Screening Instrument

1. Appearance and Condition of Both Feet

RIGHT

a. **KG NORMR**
 Normal Yes No

LEFT

b. **KG NORML**
 Normal Yes No

IF NO, CHECK ALL THAT APPLY:

- 1. Deformities **KGDEFR** Yes
- 2. Dry skin, callus **KGSKINR** Yes
- 3. Infection **KGINFR** Yes
- 4. Fissure **KGFISSR** Yes
- 5. Other, **KGOTHR** Yes

IF NO, CHECK ALL THAT APPLY:

- 1. Deformities **KGDEFL** Yes
- 2. Dry skin, callus **KGSKINL** Yes
- 3. Infection **KGINFL** Yes
- 4. Fissure **KGFISSL** Yes
- 5. Other, **KGOTHL** Yes

i. **If OTHER, specify:**

i. **If OTHER, specify:**

RIGHT

- 2. Ulceration Present Absent **KGULCRR**
- 3. Ankle Reflexes Present Present/Reinforcement Absent **KGREFR**
- 4. Vibration perception at great toe Present (<10 sec) Reduced (≥10 sec) Absent **KGTOER**
- 5. 10gm filament (record number of applications detected) applications out of 10 **KGNUMFILR**

LEFT

- 6. Ulceration Present Absent **KGULCRL**
- 7. Ankle Reflexes Present Present/Reinforcement Absent **KGREFL**
- 8. Vibration perception at great toe Present (<10 sec) Reduced (≥10 sec) Absent **KGTOEL**
- 9. 10gm filament (record number of applications detected) applications out of 10 **KGNUMFILL**

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H. History

1. Since the last annual visit, did the participant experience any of the following?

- | | Yes | No | |
|---|----------------------------|----------------------------|---------|
| a. Skin rashes? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | KGRASH |
| b. Frequent stomach pains, bloating, nausea, diarrhea, or loss of appetite? ... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | KGSTOM |
| c. Unexplained weight loss? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | KGLOSSN |
| d. Increased thirst (drinking more liquids than usual)? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | KGTHRST |
| e. Urinating more often than usual? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | KGURINT |
| f. Infection requiring medical attention? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | KGINTMA |
| g. Sprains or fractures requiring medical attention? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | KGSPRN |

2. Did a health care provider (outside the DPPOS) diagnose the participant with a new onset of the following since the last annual visit?

- | | Yes | No | |
|---|----------------------------|----------------------------|---------|
| a. Diabetes (sugar in blood or urine)? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | KGDIAB |
| b. High blood pressure? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | KGHYPER |
| c. Any lipid abnormality (high cholesterol, high triglycerides, etc.)?..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | KGLIPID |
| d. Ulcer (stomach or duodenal), or intestinal bleeding? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | KGULCR |
| e. Hepatitis? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | KGHEPAT |
| f. Cancer? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | KGCNCR |

If YES, complete an E12 Cancer Report form.

- | | | | |
|---|----------------------------|----------------------------|----------|
| g. Gallstones, gallbladder disease, or gallbladder surgery? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | KGGALL |
| h. Gout? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | KGGOUT |
| i. Thyroid disease? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | KGTHYR |
| j. Transient ischemic attack (TIA)? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | KG TIA |
| k. Kidney disease? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | KGKIDNDI |
| l. Retinopathy? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | KGRETPTY |

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I. Diabetes Management

Complete for diabetics only.

1. If diabetic, is participant taking insulin?

Yes No

KGINSUL

If YES,

a. Number of units per day

units per day

KGUNITS

b. Type of insulin regimen

Infusion pump

KGREGM

Injection

1. If injection, number of injections per day

per day

KGINJCT

PART V/ MEDICAL HISTORY

J. Interval Cardiovascular History

Ask the participant to think about the last 12 months when answering the following questions:

1. Have you had any pain or discomfort in your chest?

Yes No

KGPAIN

2. Have you had any pressure or heaviness in your chest?

Yes No

KGPRES

If Questions 1 AND 2 are NO, skip to Section K. If either are Yes, continue.

a. Do you get it when you walk uphill or hurry?

Yes No

KGHURRY

b. Do you get it when you walk at an ordinary pace on the level?

Yes No

KGLEVEL

c. When you get it in your chest, what do you do?

Stop
Slow down
Continue at same pace

KGDO

d. Does it go away when you stand still?

Yes No

KGSTILL

If YES,
1. How soon?

10 min. or less
More than 10 min.

KGSOON

e. Where do you get this pain or discomfort:

1. Sternum (central chest)?

Yes No

KGSTER

2. Left anterior chest?

Yes No

KGLCHST

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3. Left arm?

Yes 1 No 2 **KGLARM**

f. Have you ever had a severe pain across the front of your chest lasting for half an hour or more?

Yes 1 No 2 **KG30MIN**

K. Stroke / TIA

1. During the past 12 months, have you had any sudden feeling of numbness, tingling, or loss of feeling in either arm, hand, leg, foot, or face?

Yes 1 No 2 **KGNOFEEL**

If YES,

a. How long did the symptoms last?

< 1 hour 1 **KGNOFLT**
1-24 hour (s) 2
> 24 hours 3

2. During the past 12 months, have you had any sudden attacks of paralysis, or loss of use of either arm, hand, leg, or foot?

Yes 1 No 2 **KGPART**

If YES,

a. How long did the symptoms last?

< 1 hour 1 **KGPART**
1-24 hour (s) 2
> 24 hours 3

3. During the past 12 months, have you had any sudden loss of eyesight or blurring of vision for a short period of time?

Yes 1 No 2 **KGBLUR**

If YES,

a. How long did the symptoms last?

< 1 hour 1 **KGBLURT**
1-24 hour (s) 2
> 24 hours 3

4. During the past 12 months, have you had any sudden attacks of changes in speech, loss of speech or inability to say words for more than two minutes?

Yes 1 No 2 **KGLUR**

If YES,

a. How long did the symptoms last?

< 1 hour 1 **KGLURT**
1-24 hour (s) 2
> 24 hours 3

5. During the past 12 months, have you had any spells of dizziness, difficulty in walking, lightheadedness or loss of balance?

Yes 1 No 2 **KGDIZY**

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If YES,

a. How long did the symptoms last?

< 1 hour	<input type="text" value="1"/>	KGDIZYT
1-24 hour (s)	<input type="text" value="2"/>	
> 24 hours	<input type="text" value="3"/>	

PART VI / INTERVAL DRINKING, SMOKING, ANTI-INFLAMMATORY MEDICATION, & ROUTINE CARE HISTORY

L. Drinking Status

1. During the past 12 months, have you consumed an average of at least one alcoholic beverage per week?

Yes	<input type="text" value="1"/>	No	<input type="text" value="2"/>	KGWK
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If YES, for the most recent normal (i.e., usual) week:

a. How many 12 oz. bottles of beer did you consume during the past 7 days?

<input type="text"/>	<input type="text"/>	12 oz Bottles	KGBEER
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b. How many 4 oz. glasses of wine did you consume during the past 7 days?

<input type="text"/>	<input type="text"/>	4 oz Glasses	KGWINE
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c. How many 1.5 oz. shots of hard liquor or mixed drinks did you consume during the past 7 days?

<input type="text"/>	<input type="text"/>	1.5 oz Shots	KGMIXD
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2. During the past 12 months, have you ever consumed 7 or more alcoholic beverages (including mixed drinks, shots, beer, and/or wine) within a 24-hour period?

Yes	<input type="text" value="1"/>	No	<input type="text" value="2"/>	KGBINGE
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If YES,

a. About how often is this (that you have had 7 or more drinks within a 24-hour period)?

No answer	<input type="text" value="1"/>	KGBTIME
Rare or less than once a month	<input type="text" value="2"/>	
1-3 times per month	<input type="text" value="3"/>	
Once a week or more	<input type="text" value="4"/>	

M. Smoking Status

1. During the past 30 days, have you smoked any cigarettes?

Yes	<input type="text" value="1"/>	No	<input type="text" value="2"/>	KGSMOK
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If YES,

a. On average, how many cigarettes per day?

<input type="text"/>	<input type="text"/>	KGSDAY	cigarettes per day
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N. Anti-inflammatory Medication Status

1. During an average week, how often do you take one or more aspirin tablets regardless of dosage?

Never	<input type="text" value="1"/>	KGASPIR
Less than 1 day per week	<input type="text" value="2"/>	
1 or 2 days per week	<input type="text" value="3"/>	
3 to 4 days per week (includes every other day)	<input type="text" value="4"/>	
5 or 6 days per week	<input type="text" value="5"/>	
Every day	<input type="text" value="6"/>	

If you take aspirin (options 2-6),

	Type of aspirin	Do you take this type of aspirin?		If YES, 1. On days you use aspirin, what is the total number of pills you take?
		Yes	No	
a.	Baby-strength aspirin (81mg)	<input type="text" value="1"/>	<input type="text" value="2"/>	KGASPBABY <input type="text" value=""/> <input type="text" value=""/> . <input type="text" value=""/>
b.	Regular-strength aspirin (325mg)	<input type="text" value="1"/>	<input type="text" value="2"/>	KGASPBABNO <input type="text" value=""/> <input type="text" value=""/> . <input type="text" value=""/>
c.	Extra -strength aspirin (500mg)	<input type="text" value="1"/>	<input type="text" value="2"/>	KGASPREG <input type="text" value=""/> <input type="text" value=""/> . <input type="text" value=""/>
				KGASPREGNO <input type="text" value=""/> <input type="text" value=""/> . <input type="text" value=""/>
				KGASPEX <input type="text" value=""/> <input type="text" value=""/> . <input type="text" value=""/>
				KGASPEXNO <input type="text" value=""/> <input type="text" value=""/> . <input type="text" value=""/>

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2. Has the participant taken a non-prescription non-steroidal anti-inflammatory drug (NSAID) other than aspirin in the past month? (Many pain relievers are NSAIDs, including ibuprofen, Advil, Motrin, and Aleve)
- Yes No
- KGNSAID**

If YES,

	Type of NSAID	Did you take this NSAID?		If YES, 1. On average how many days per month?	2. On days you use the NSAID, what is the total number of pills you take?
		Yes	No		
a.	Ibuprofen (e.g. Advil, Motrin, Nuprin)	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value=""/> <input type="text" value=""/> days	<input type="text" value=""/> <input type="text" value=""/> pills
b.	Naproxen (e.g. Aleve, Anaprox, Naprosyn, Naprelan)	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value=""/> <input type="text" value=""/> days	<input type="text" value=""/> <input type="text" value=""/> pills
c.	Other	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value=""/> <input type="text" value=""/> days	<input type="text" value=""/> <input type="text" value=""/> pills
3. If OTHER, specify:		<input type="text" value="KGNSAIDSP"/>			

O. Routine Medical Care

1. During the past 3 months, how many times have you, outside the DPPOS: (none = 0)
- a. called a health care provider (for a specific issue/concern)? time(s) **KGCHCD**
 - b. had a regularly scheduled out-patient visit(s)? time(s) **KGCOPV**
 - c. had urgent care visit(s) (i.e. doctor's office, clinic; not to emergency room)? time(s) **KGUCV**
 - d. had an emergency room visit(s)? time(s) **KGCERV**
2. During the past 3 months, how many days have you lost from school, work, or household activities due to illness or injury or medical care including visits related to the DPPOS? (round to nearest half day)
- day(s) **KG CLOST**

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PART VII / CONCOMITANT MEDICATIONS

Complete this section for all participants.

P. Concomitant Medications

1. Has the participant taken any **PRESCRIPTION** medications within the past 2 weeks (excluding study metformin)?

Yes No **KGRXDQ**

If YES,

a. Total number of medications taken (including any medications listed on supplemental sheets)

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KGTOTMEDS

b. List medications below: **KGDRUG1-30**

	Medicine Description	Route
1.	<input type="text"/>	<input type="text"/>
2.	<input type="text"/>	<input type="text"/>
3.	<input type="text"/>	<input type="text"/>
4.	<input type="text"/>	<input type="text"/>
5.	<input type="text"/>	<input type="text"/>
6.	<input type="text"/>	<input type="text"/>
7.	<input type="text"/>	<input type="text"/>
8.	<input type="text"/>	<input type="text"/>
9.	<input type="text"/>	<input type="text"/>
10.	<input type="text"/>	<input type="text"/>
11.	<input type="text"/>	<input type="text"/>
12.	<input type="text"/>	<input type="text"/>
13.	<input type="text"/>	<input type="text"/>
14.	<input type="text"/>	<input type="text"/>
15.	<input type="text"/>	<input type="text"/>

Specify additional medications by appending the CONMED supplemental sheet to this form as needed.

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IF THIS IS A MID-YEAR VISIT, STOP: FORM IS COMPLETE. IF THIS IS AN ANNUAL VISIT, CONTINUE.

Q. Nutritional Supplements

Multivitamins are identified by the word multivitamin in the bottle label or if the number of active ingredients are 5 or more. If there are fewer than 5 active ingredients in a supplement, include them in Question Q3. Multivitamins should exclude B-Complex and instead the relevant B-vitamins should be included in the specific supplement list in Question Q3.

1. Has the participant taken any **non-prescription** oral multivitamins at least once a week in the past 12 months? Yes ¹ No ²
KGMULTIV

2. Has the participant received any Vitamin B12 shots in the past 12 months? Yes ¹ No ²
KGB12SHOT

If YES,

a. Number of shots received in the past 12 months shots KGSHTNO

3. Has the participant taken any **non-prescription** oral supplements other than multivitamins at least once a week in the past 12 months? Yes ¹ No ²

If YES,

KGSUP
KGSUPP

KGSUPPMO

KGOMEGA

KGVITA

KGVITB6

KGVITB12

KGVITC

KGVITD

KGVITE

KGCAL

KGCHRO

KGFOL

KGIRON

KGMAG

KGPOT

KGSEL

KGZINC

Type of supplement KGSUPPDSC	Did the participant take this supplement?		If YES, 1. Number of months used in the past 12 months?	KGTOTSUPP 2. Average number of doses per week?	
	Yes	No		KGSUPPNO	
a. Omega 3 (fish oil)	<input type="text"/> ¹	<input type="text"/> ²	<input type="text"/> <input type="text"/> months	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
b. Vitamin A (not Beta-carotene)	<input type="text"/> ¹	<input type="text"/> ²	<input type="text"/> <input type="text"/> months	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
c. Vitamin B6	<input type="text"/> ¹	<input type="text"/> ²	<input type="text"/> <input type="text"/> months	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
d. Vitamin B12	<input type="text"/> ¹	<input type="text"/> ²	<input type="text"/> <input type="text"/> months	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
e. Vitamin C (with or without rose hips)	<input type="text"/> ¹	<input type="text"/> ²	<input type="text"/> <input type="text"/> months	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
f. Vitamin D	<input type="text"/> ¹	<input type="text"/> ²	<input type="text"/> <input type="text"/> months	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
g. Vitamin E	<input type="text"/> ¹	<input type="text"/> ²	<input type="text"/> <input type="text"/> months	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
h. Calcium	<input type="text"/> ¹	<input type="text"/> ²	<input type="text"/> <input type="text"/> months	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
i. Chromium	<input type="text"/> ¹	<input type="text"/> ²	<input type="text"/> <input type="text"/> months	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
j. Folate (Folic Acid)	<input type="text"/> ¹	<input type="text"/> ²	<input type="text"/> <input type="text"/> months	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
k. Iron	<input type="text"/> ¹	<input type="text"/> ²	<input type="text"/> <input type="text"/> months	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
l. Magnesium	<input type="text"/> ¹	<input type="text"/> ²	<input type="text"/> <input type="text"/> months	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
m. Potassium	<input type="text"/> ¹	<input type="text"/> ²	<input type="text"/> <input type="text"/> months	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
n. Selenium	<input type="text"/> ¹	<input type="text"/> ²	<input type="text"/> <input type="text"/> months	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
o. Zinc	<input type="text"/> ¹	<input type="text"/> ²	<input type="text"/> <input type="text"/> months	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>