


Compound V503	Protocol 002-00	
-------------------------	---------------------------	---

Allocation Number

Vaccination Report Card (9 - 15 Years of Age)


*Only the PARENT or GUARDIAN of the subject should complete this vaccination report card. Corrections to the vaccination report card by the parent or guardian should be dated and initialed by the parent or guardian.
The STUDY NURSE will enter the dates where needed.*

Complete this card for **15 days after vaccination** (until _____)
month/day/year
and return the card to the study site when it is complete.

Study Personnel Telephone Number: _____

Parent or Guardian's Comments:

Study Site Personnel Comments:

Compound V503	Protocol 002-00	
-------------------------	---------------------------	---

Allocation Number

TEMPERATURE MEASUREMENT

It is important that you take your child's temperature every day starting with the day of vaccination through Day 5.

Take your child's temperature orally and record this temperature in the appropriate box below.

Take your child's temperature in the evening whenever possible. If you need to take your child's temperature more than once during a day, record the highest temperature taken that day.

TAKE ORAL TEMPERATURE EACH DAY		
DAY	DATE (month/day/year)	ORAL TEMPERATURE
1		
2		
3		
4		
5		

I have reviewed this information.	
Staff's initials:	Date:

INSTRUCTIONS FOR INJECTION SITE REACTIONS:

On the following pages entitled "Injection Site Reactions", please measure any **swelling** or **redness** AT THE INJECTION SITE.

Estimate the **size** of the reaction at its largest from edge to edge. Use the ruler marks along the bottom of the page.

Mark the box that best describes the size of the reaction:

1 if the greatest width is anywhere in the area marked 1 (**Example A**)

2 if the greatest width is anywhere in the area marked 2

3 if the greatest width is anywhere in the area marked 3 (**Example B**)

Over 3 if the greatest width is in any area marked with a number over 3.

Write in the number. (**Example C**)

If the reaction is wider than the area marked 7, write in 8.

On the following pages entitled "Injection Site Reactions", please estimate the severity of any **pain or tenderness** or **other reactions** AT THE INJECTION SITE.

Mark the box that best describes the severity of the reaction using the following definitions:

mild is awareness of symptom, but easily tolerated

moderate is definitely acting like something is wrong

severe is extremely distressed or unable to do usual activities

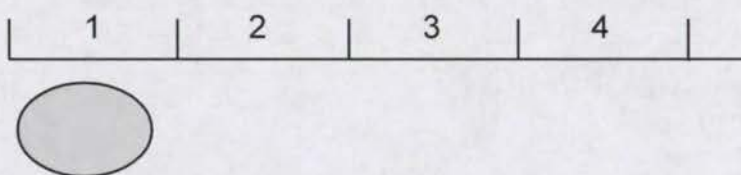
Complete one column each day, starting with Day 1 (the day of vaccination - 4 hours after injection). If the reaction continues past Day 5, please write in the last date it was present.

If an injection site reaction begins after Day 5, please estimate the severity of the reaction in the box at the bottom of the pages entitled "Injection Site Reactions".

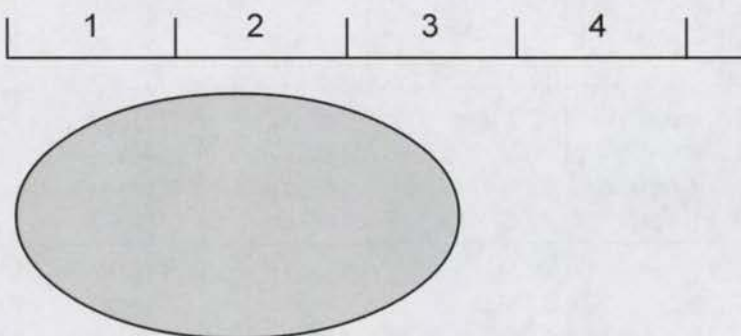
1	2	3	4	5	6	7	8 →
---	---	---	---	---	---	---	-----

EXAMPLES FOR MEASURING THE SIZE OF REACTIONS:

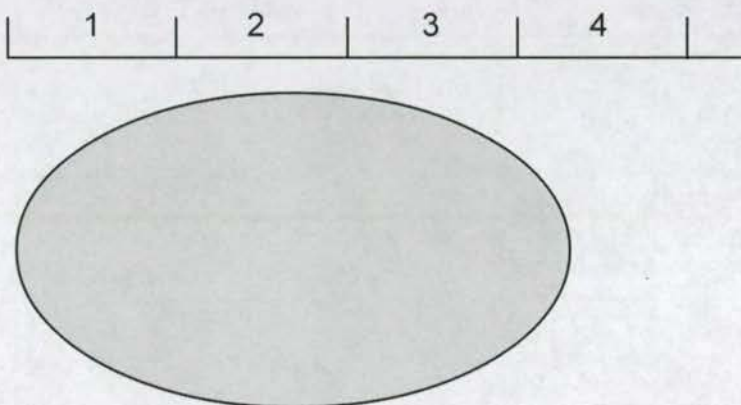
Example A: This reaction falls in the area marked 1 at its largest, so you would check the box marked "1."



Example B: This reaction falls in the area marked 3 at its largest, so you would check the box marked "3."



Example C: This reaction falls in the area marked 4 at its largest, so you would check the box marked "Over 3" and write in a 4.



Compound V503	Protocol 002-00	
-------------------------	---------------------------	--

Allocation Number

INJECTION SITE REACTIONS

Complete one copy of this page per injection site. Indicate the injection site for this page by checking one box below.

Injection Site (check one per page): Right Arm Left Arm Right Thigh Left Thigh
 Other _____


	DAY 1 Vaccination Day <small>month/day/year</small>	DAY 2 <small>month/day/year</small>	DAY 3 <small>month/day/year</small>	DAY 4 <small>month/day/year</small>	DAY 5 <small>month/day/year</small>	LAST DATE REACTION PRESENT <small>month/day/year</small>
SWELLING	<input type="checkbox"/> None <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> over 3: ____	<input type="checkbox"/> None <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> over 3: ____	<input type="checkbox"/> None <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> over 3: ____	<input type="checkbox"/> None <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> over 3: ____	<input type="checkbox"/> None <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> over 3: ____	<small>month/day/year</small>
REDNESS	<input type="checkbox"/> None <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> over 3: ____	<input type="checkbox"/> None <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> over 3: ____	<input type="checkbox"/> None <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> over 3: ____	<input type="checkbox"/> None <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> over 3: ____	<input type="checkbox"/> None <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> over 3: ____	<small>month/day/year</small>

PAIN or TENDERNESS	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<small>month/day/year</small>
OTHER INJECTION SITE REACTION (specify):	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<small>month/day/year</small>
OTHER INJECTION SITE REACTION (specify):	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<small>month/day/year</small>

If an injection site reaction began 6 or more days after your child's vaccination, please record it below. Record the date it started and the last date it was present. Mark the box that best describes the severity of the injection site reaction.

INJECTION SITE REACTIONS BEGINNING 6 OR MORE DAYS AFTER VACCINATION	DATE (month/day/year)		SEVERITY
	Started	Last Present	
			<input type="checkbox"/> mild <input type="checkbox"/> moderate <input type="checkbox"/> severe
			<input type="checkbox"/> mild <input type="checkbox"/> moderate <input type="checkbox"/> severe

1 2 3 4 5 6 7 8 →

Compound V503	Protocol 002-00	
-------------------------	---------------------------	---

Allocation Number

Adult Vaccination Report Card

*Only the SUBJECT should complete this vaccination report card. Corrections to the vaccination report card by the subject should be dated and initialed by the subject.
The STUDY NURSE will enter the dates where needed.*

Complete this card for **15 days after vaccination** (until)
and return the card to the study site when it is complete.

Study Personnel Telephone Number: _____

Subject's Comments:

Study Site Personnel Comments:

Compound V503	Protocol 002-00	
-------------------------	---------------------------	---

Allocation Number

TEMPERATURE MEASUREMENT

It is important that you take your temperature every day for 5 days starting with the day of vaccination.

Take your temperature orally and record this temperature in the appropriate box below.

Take your temperature in the evening whenever possible. If you need to take your temperature more than once during a day, record the highest temperature taken that day.

TAKE ORAL TEMPERATURE EACH DAY		
DAY	DATE (month/day/year)	ORAL TEMPERATURE
1		
2		
3		
4		
5		

I have reviewed this information.	
Staff's initials:	Date:

INSTRUCTIONS FOR INJECTION SITE REACTIONS:

On the following pages entitled "Injection Site Reactions", please measure any **swelling** or **redness** AT THE INJECTION SITE.

Estimate the **size** of the reaction at its largest from edge to edge. Use the ruler marks along the bottom of the page.

Mark the box that best describes the size of the reaction:

- 1** if the greatest width is anywhere in the area marked 1 (**Example A**)
- 2** if the greatest width is anywhere in the area marked 2
- 3** if the greatest width is anywhere in the area marked 3 (**Example B**)
- Over 3** if the greatest width is in any area marked with a number over 3.
Write in the number. (Example C)
- If the reaction is wider than the area marked 7, write in 8.

On the following pages entitled "Injection Site Reactions", please estimate the severity of any **pain or tenderness** or **other reactions** AT THE INJECTION SITE.

Mark the box that best describes the severity of the reaction using the following definitions:

- mild** is awareness of symptom, but easily tolerated
- moderate** is discomfort enough to cause interference with usual activities
- severe** is incapacitating with inability to work or do usual activity

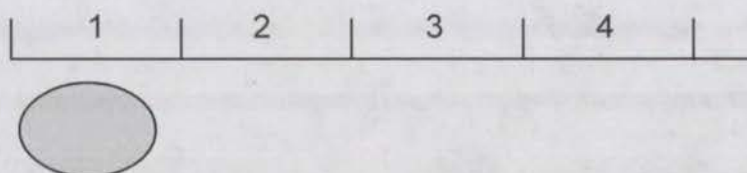
Complete one column each day, starting with Day 1 (the day of vaccination - 4 hours after injection). If the reaction continues past Day 5, please write in the last date it was present.

If an injection site reaction begins after Day 5, please estimate the severity of the reaction in the box at the bottom of the pages entitled "Injection Site Reaction".

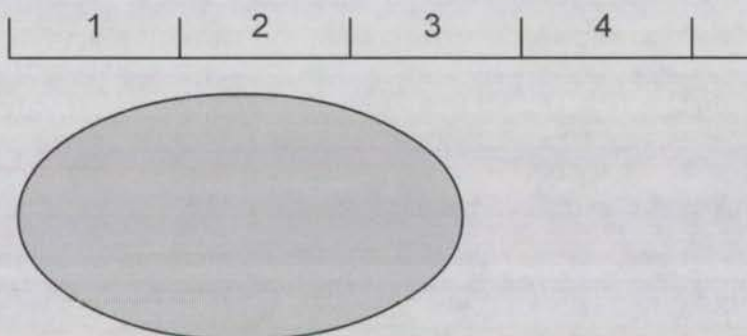
1	2	3	4	5	6	7	8 →
---	---	---	---	---	---	---	-----

EXAMPLES FOR MEASURING THE SIZE OF REACTIONS:

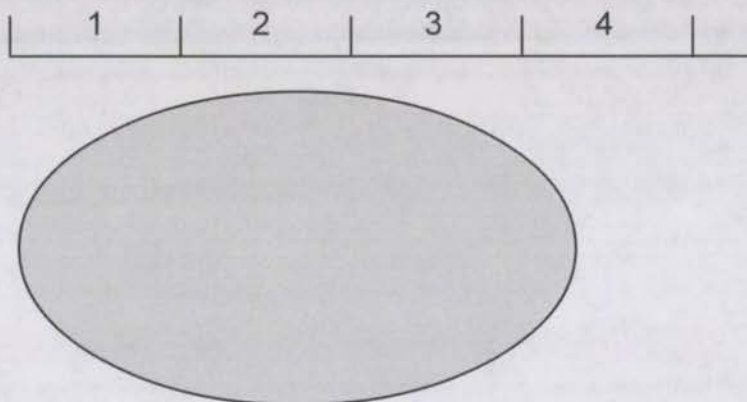
Example A: This reaction falls in the area marked 1 at its largest, so you would check the box marked "1".



Example B: This reaction falls in the area marked 3 at its largest, so you would check the box marked "3".



Example C: This reaction falls in the area marked 4 at its largest, so you would check the box marked "Over 3" and write in a 4.



Compound V503	Protocol 002-00	
-------------------------	---------------------------	---

Allocation Number

INJECTION SITE REACTIONS

Complete one copy of this page per injection site. Indicate the injection site for this page by checking one box below.

Injection Site (*check one per page*): Right Arm Left Arm Other _____
 Right Thigh Left Thigh

	DAY 1 Vaccination Day <small>month/day/year</small>	DAY 2 <small>month/day/year</small>	DAY 3 <small>month/day/year</small>	DAY 4 <small>month/day/year</small>	DAY 5 <small>month/day/year</small>	LAST DATE REACTION PRESENT <small>month/day/year</small>
SWELLING	<input type="checkbox"/> None <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> over 3: ____	<input type="checkbox"/> None <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> over 3: ____	<input type="checkbox"/> None <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> over 3: ____	<input type="checkbox"/> None <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> over 3: ____	<input type="checkbox"/> None <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> over 3: ____	<small>month/day/year</small>
REDNESS	<input type="checkbox"/> None <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> over 3: ____	<input type="checkbox"/> None <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> over 3: ____	<input type="checkbox"/> None <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> over 3: ____	<input type="checkbox"/> None <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> over 3: ____	<input type="checkbox"/> None <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> over 3: ____	<small>month/day/year</small>

PAIN or TENDERNESS	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<small>month/day/year</small>
OTHER INJECTION SITE REACTION (specify):	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<small>month/day/year</small>
OTHER INJECTION SITE REACTION (specify):	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<small>month/day/year</small>

If an injection site reaction **began** 6 or more days after your vaccination, please record it below. Record the date it **started** and the **last date it was present**. Mark the box that best describes the severity of the injection site reaction.

INJECTION SITE REACTIONS BEGINNING 6 OR MORE DAYS AFTER VACCINATION	DATE (month/day/year)		SEVERITY
	Started	Last Present	
			<input type="checkbox"/> mild <input type="checkbox"/> moderate <input type="checkbox"/> severe
			<input type="checkbox"/> mild <input type="checkbox"/> moderate <input type="checkbox"/> severe

1	2	3	4	5	6	7	8 →
---	---	---	---	---	---	---	-----

